Simmons & Simmons LLP
Pièce
N° 3
J 031
Avocats à la cour

Conceptus®

Corrosion Susceptibility on Conceptus Essure Micro-insert: 6 Month Report

VR-0191.PV.Rev2

Approvals:

	Name	Signature	Date
Originator	Elisa Aldridge	Elisa Aldridge	1-26-2004
Research & Development	Chris Stout		2-6-04
Regulatory Affairs/ Clinical Research	Ed Sinclair		2-6-2004
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Operations/ Manufacturing			2/12/04

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Total of 85 pages
PW 2-17-04

1.0 SUMMARY

- The Essure Micro-insert passes the corrosion susceptibility bench test.
- 54 Essure Micro-inserts were tested for up to six months in a worst-case bench environment.
- The daily leaching rate of nickel and tin ions released are at least 2000 times less than everyday intake of food and water and exposure to environment.
- The daily leaching rate of chromium is below the detection limit.
- The Essure Micro-insert maintained mechanical integrity during the six months of exposure to a corrosive saline environment.

2.0 PURPOSE

The purpose of the corrosion bench test was to measure the levels of potentially harmful metal ions released, and assess loss of mechanical integrity and overall corrosion damage to Essure Micro-inserts over a six-month period in a worst case, corrosive bench-top environment.

3.0 SCOPE

3.1 This report covers all six months of the corrosion bench test. The first revision of this report was an interim report covering only the first three months of data.

3.2 The test articles were Essure Micro-inserts, internally known as Device Subassemblies, E0648-02.

4.0 REFERENCE DOCUMENTS

4.1	E0648-02	Device Subassembly
4.2	VP-0191.PV, Rev 1	Protocol corresponding to this validation
4.3	VP-0191.PV, A01	Addendum to protocol

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4.4	VR-0191.PV, Rev 1	3 month interim report corresponding to this validation
4.5	VR-0213.PV, Rev2	Corrosion Properties of the Essure Implant: X-Ray Examination Evaluation
4.6	SOP-01046, Rev K	Validation Policy
4.7	DR 069, Rev 0	Verification Bench Testing
4.8	DR 047, Rev 0	Summary Report of Essure Micro-insert Corrosion Evaluation
4.9	VP-0246.PV.Rev1	Product Validation Protocol: Biocompatibility Testing of the Essure System
4.10	VR-0246.PV.Rev1	Product Validation Report: Biocompatibility Testing of the Essure System

5.0 ATTACHMENTS AND APPENDICES

5.1	Appendix 1	Table of Cumulative Leaching Rates
5.2	Appendix 2	Table of Disruptive Leaching Rates
5.3	Appendix 3	Build records for test samples
5.4	Appendix 4	Documentation of procedure (copies of lab notebook pages)
5.5	Appendix 5	Leaching analysis data sheets.
5.6	Attachment 1	VP-0191.PV.Rev1 (copy)
5.7	Attachment 2	VP-0191.PV A01 (copy)

6.0 BACKGROUND

No standard exists for corrosion testing of medical devices intended for implantation in the fallopian tubes. Therefore, this study was designed for the specific requirements of the Essure Micro-insert. The results of this study should be considered together with the results of clinical evaluations to determine the corrosion susceptibility of the device. See DR047, Rev 0.

6.1 Leaching Rate of Metal Ions

This bench test is designed to measure the leaching rate of potentially harmful metal ions. The Essure Micro-insert is made of the materials listed in **Table 1** below.

Table 1: Material composition of components of the Essure Micro-insert.

Components	Material	Material Composition
Outer Coil	Chromium doped Nitinol (Nickel-Titanium)	56% Nickel, 44% Titanium, trace Chromium
Inner Coil, Thread Coil	316L stainless steel	apx. 62.5% Iron, 17.6% Chromium, 14.5% Nickel
Stopper Band, Platinum Band, Platinum Ring, Bump	Platinum-Iridium	90% Platinum, 10% Iridium
Solder	Tin-Silver	95% Tin, 5% Silver
Fiber	PET polyester, white	≥ 92% Polyester, < 5% TiO_2, < 3% fiber lubricants

From this list of materials, three metal ions have been identified as potentially harmful: nickel, chromium, and tin. Nickel is of most concern, because exposure to nickel is known to cause nickel allergy. The leaching rates of other metals were not measured, because they are not known to have harmful effects on the human body.

This study seeks to quantify the leaching rate of the three metal ions of concern and compare them to known human intake levels. The study is not designed to determine the effects of corrosion products on the human body. Instead, the biological effects of implanting the Essure Micro-insert have been addressed through biocompatibility testing as described in VP-0246.PV.Rev1 and VR-0246.PV.Rev1.

6.2 Mechanical Integrity of Micro-insert

This corrosion study is also designed to determine whether or not the mechanical integrity of the Micro-inserts is maintained after exposure to a corrosive environment for three months. During the first three months of implantation, the outer coil holds the inner coil and polyester fibers in place while tissue grows into the Micro-insert. After tissue ingrowth has occurred, the Micro-insert is held in place by tissue. If corrosion should cause the inner coil and outer coil to completely come apart during the first three months of implantation, and then a subsequent migration of one of the detached components were to occur, it is possible that the Micro-insert may not be held in place long enough to stimulate complete tissue ingrowth and blockage of the fallopian tube. The Micro-insert could not be relied on for contraception if this situation occurred.

6.3 General Corrosion Susceptibility

In addition, the SEM images created as part of this study provide highly detailed images that can be examined for signs of unexpected corrosion.

6.4 Bench Top Corrosion Environment

The bench corrosion environment was designed to be potentially more corrosive than the *in-vivo* environment. The implants were maintained in 37° C physiological saline similar to the environment of the fallopian tubes. The saline was buffered to be slightly acidic, because the uterus near the fallopian tubes is known to have a pH from 6.3 to 7.1[1,2]. It was not known whether corrosion would be worse in an enclosed environment or an environment flushed by saline, so samples were tested in two different ways. One group of samples was left in saline for up to 180 days. Another group of samples was also tested for 180 days but had the saline periodically replaced with fresh saline.

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[1] Feo L.G. (1955). "The pH of the Human Uterine Cavity in Situ"; Am. J. Obst. & Gynec: 60-64

[2] Kudla T. (1964). "The Evaluation of the Hydrogene Potentions (pH) of the Uterine Cavity In Situ in the Course of the Menstrual Cycle in Comparison with Results of Endometrial Biopsies and the Measurements of the Basal Body Temperature."

The X-ray evaluation of clinical data from the Phase II and Pivotal trials showed no measurable loss of solder due to corrosion as compared to visible loss of solder in the bench study, validating the design of the bench study to simulate a potentially more corrosive environment on the bench *in-vivo*. See the three month summary report, DR047, Rev 0.

7.0 PROCEDURE

7.1 Samples

7.1.1 Samples were Device Subassemblies E0648-02, lot # RD0127001. Build documentation is included in Appendix 3.

7.1.2 54 Device Subassemblies were tested. Two Device Subassemblies were tested per vial to model the number of implants one patient would receive.

7.1.3 6 Device Subassemblies (in three vials) were used as controls.

7.2 Procedure

The corrosion bench study was performed according to the procedure in VP-0191.PV.Rev1 and A01. Refer to Attachments 1 and 2. Documentation of the procedure was recorded in lab notebooks. Photocopies of the lab notebook pages are included in Appendix 4. Protocol deviations are explained in Section 10.

Two types of tests were performed on the samples. Group A "cumulative" samples were placed in saline in a heated water bath for periods of time ranging from 7 days to 180 days. At the specified time, the vials were removed from the heated water bath, the saline was sent out for analysis, and the Micro-inserts were cleaned and examined. Group B "disruptive" samples were placed in saline in a heated water bath. At specified times, the saline was removed for analysis, and fresh saline was added to the vials. At 180 days, the vials were removed from the heated water bath, the remaining saline was sent out for analysis, and the Micro-inserts were cleaned and examined. Figure 1 shows the time each sample remained in saline.

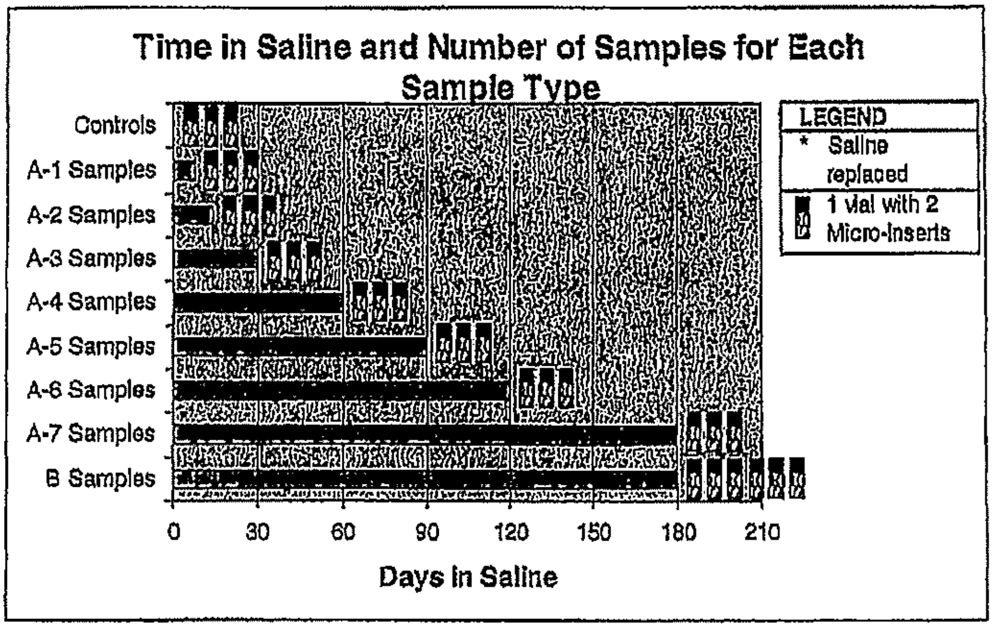

Figure 1: Graphical description of number of samples and days in saline.

7.3 Equipment

Only calibrated equipment was used, except in the case of the heated water bath. Because the water bath was not calibrated, a calibrated electronic temperature gage was used to monitor the water bath temperature. See the protocol addendum located in Attachment 2.

7.3.1 Heated water bath
7.3.2 Electronic temperature gage
7.3.3 Ultrasonic cleaner
7.3.4 Microscope
7.3.5 pH test strips

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7.4 Personnel

7.4.1 Sample preparation and handling was performed by R&D engineers, Christian Lowe and Elisa Aldridge, and by R&D technician, Cheryl Swanson.

7.4.2 SEM imaging was performed by SEM scientist Jane Wheeler at Charles Evans & Associates.

7.4.3 Metal leaching analysis was performed by analyst DH at Scientific Environmental Laboratories.

7.4.4 Jay Yang, PhD of Global Nitinol Technologies was consulted to assist in designing the study and interpreting the results. Jay Yang wrote the protocol and three month report, VP-0191.PV.Rev1 and VR-0191.PV.Rev1.

8.0 ACCEPTANCE CRITERIA

8.1 Leaching Rate of Nickel

The leaching rate of nickel ions from the samples must be lower than the average levels of human intake of nickel from diet and the environment.

8.2 Mechanical Integrity

The Micro-inserts must maintain mechanical integrity for at least three months. That is, each Micro-insert must still be in one piece after exposure to a corrosive saline environment for three months. In particular, the fibered inner coil must remain attached to the outer coil.

9.0 RESULTS AND DISCUSSION

The test passed both acceptance criteria. The leaching rate of nickel and tin ions released due to corrosion were at least 2000 times lower than the daily human intake of these metal ions from the diet and environment. The leaching rate of chromium was below the detection limit. All of the samples tested maintained mechanical integrity, not just for three months, but for all six months of the study.

9.1 Metal Ion Leaching Analysis Summary

The levels of nickel and tin ions released into the solution were found to be at least 2000 times below the average levels of human intake of these ions from diet and the environment[3]. The level of chromium released was below the detection limit. According to published data, the normal human intake of nickel and tin from food and water and the observed highest measured leaching rates for the three metals monitored are as follows:

Table 2: Highest Metal Leaching Rates Compared to Normal Human Intake

Metal	Normal Human Daily Intake[3]	Highest Measured Leaching Rates
Nickel	300 µg/day	0.14 µg/day
Tin	100,000 µg/day	27 µg/day
Chromium	no published data is available	less than 0.03 µg/day (below detection limit)

9.1.1 Metal Ion Leaching Analysis Cumulative Data

Figure 2 and Figure 3 show the leaching rate of nickel and tin as analyzed in the cumulative test (A samples). The leaching rate of chromium was below the detection limit at all time points. The test was an evaluation of the cumulative metal ion release at each time point (7 days, 14 days, 30 days, 60 days, 90 days, 120 days, and 180 days). The samples were placed in a vial of saline and left in a heated water bath for the number of days indicated, and the saline was removed and analyzed at the end of the time period indicated. Table 3 containing the calculated data is located in Appendix 1. The raw data is located in Appendix 5.

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[3] Medical and Biological Effects of Environmental Pollutants, published by the National Academy of Sciences, Washington, D.C., 1975.

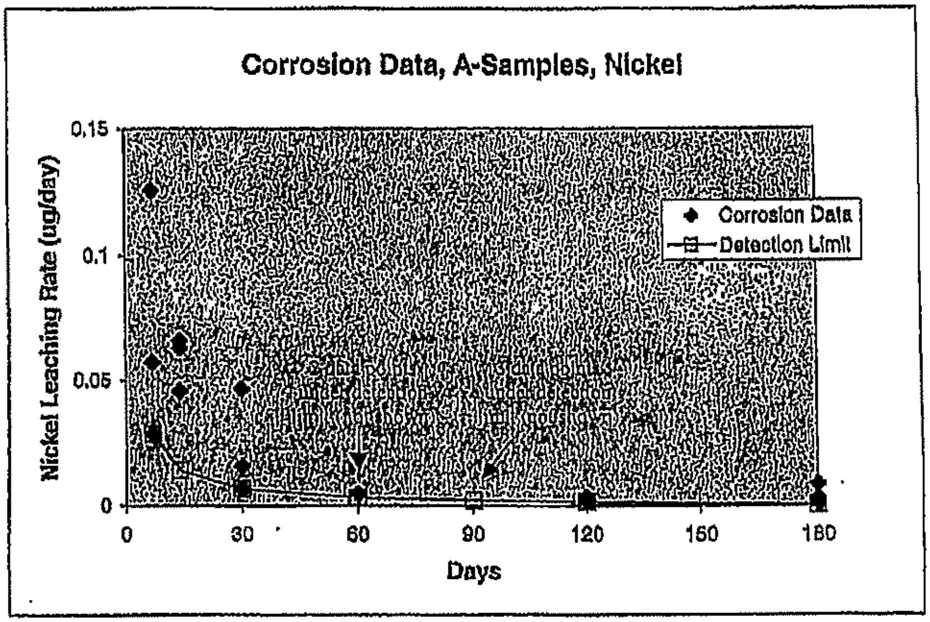

Figure 2: Leaching rate of Nickel for Cumulative Samples.

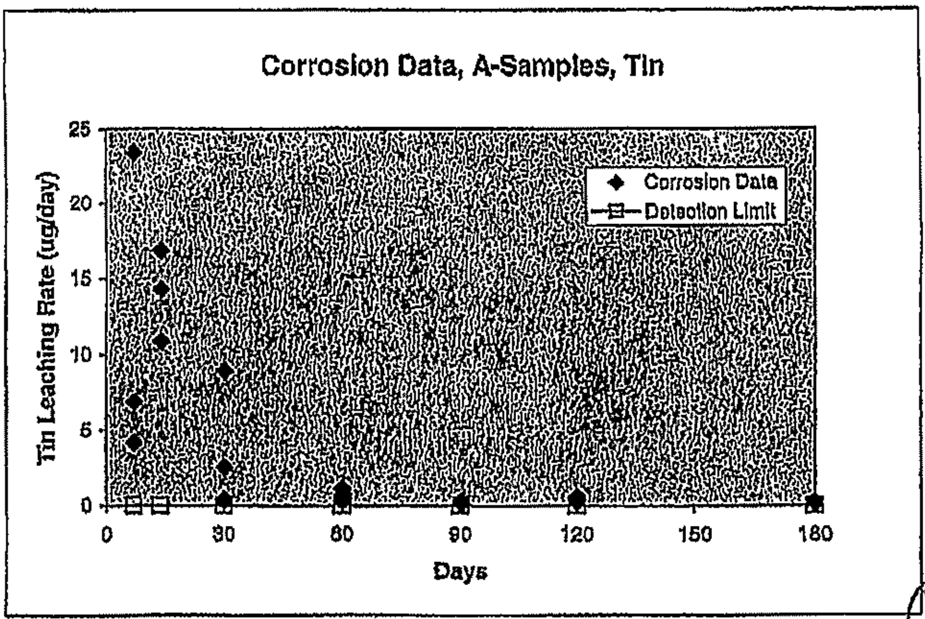

Figure 3: Leaching rate of Tin for Cumulative Samples.

9.1.2 Metal Ion Leaching Analysis Disruptive Data

Figure 4 and **Figure 5** show the leaching rate of nickel and tin as analyzed in the disruptive test (B samples). The leaching rate of nickel was below the detection limit at all time points except 7 days and 180 days. The leaching rate of chromium was below the detection limit at all time points. The test evaluated metal ion release for 0-7 days, 7-14 days, 14-30 days, 30-60 days, 60-90 days, 90-120 days, and 120-180 days, for a single set of samples and was termed the "disruptive test". At each time indicated, the saline was removed for analysis, and fresh saline was added to the vials containing the Micro-insert samples. The data for the "disruptive test" is included in **Table 4** in Appendix 2. Raw data is located in Appendix 5.

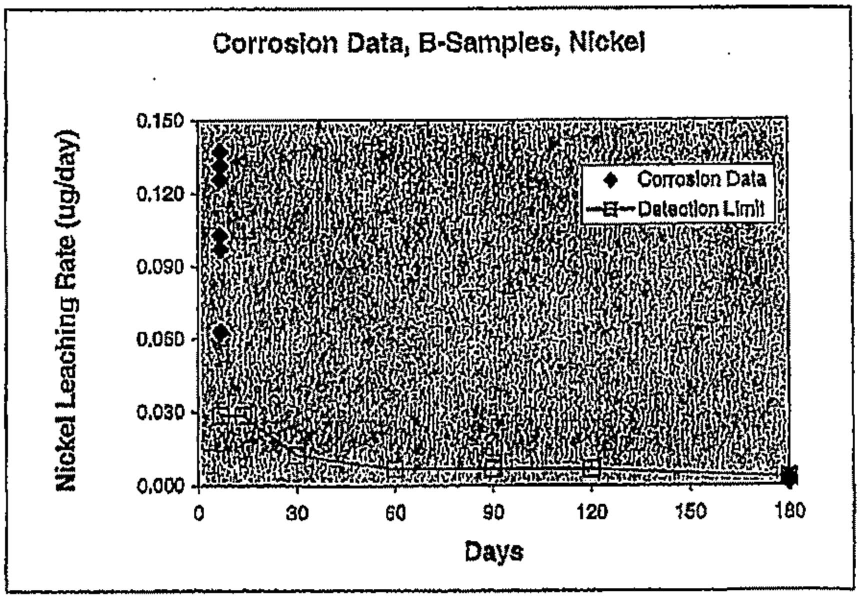

Figure 4: Leaching rate of Nickel for Disruptive Samples.

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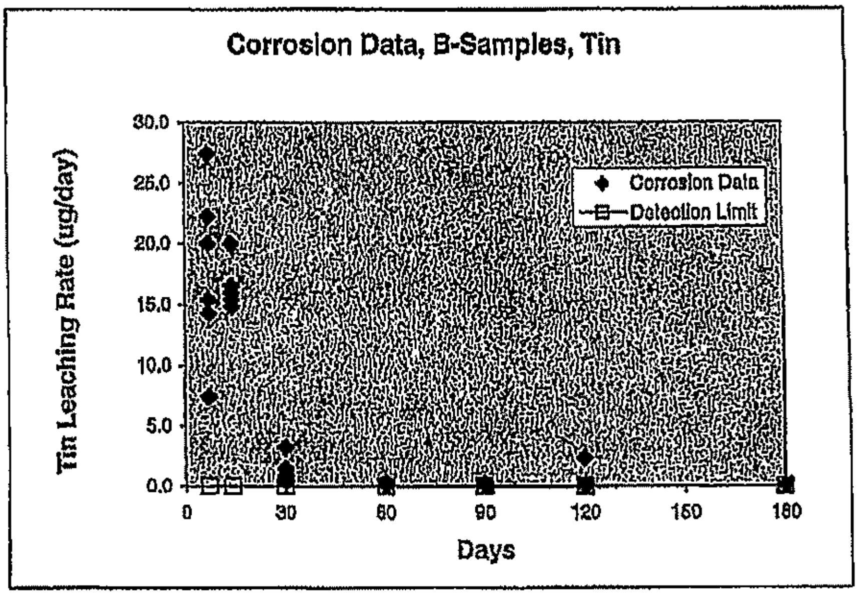

Figure 5: Leaching rate of Tin for Disruptive Samples.

9.2 Mechanical Integrity

The samples passed the acceptance criteria for mechanical integrity. All of the samples tested maintained mechanical integrity, not just for three months, but for all six months of the study.

After the Micro-insert samples were removed from the vials of solution, they were cleaned in an ultrasonic bath, dried, and examined using scanning electron microscopy (SEM). No Micro-inserts showed loss of mechanical integrity. In all cases, the outer coil remained attached to the fibered inner coil.

9.3 Examination for Signs of Corrosion

As expected, the solder showed signs of corrosion resulting in pitting and increasing porosity with the worst corrosion damage on the ball tip. At the three-month time point, approximately 25-50% of the solder had corroded.

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At the six-month time point, the ball tips of some of the samples were almost completely corroded, but all of the solder bonds continued to hold together. In all cases, the outer coil remained attached to the fibered inner coil. This is an acceptable level of solder corrosion, because it did not result in the loss of mechanical integrity. No other components showed signs of corrosion.

10.0 DEVIATIONS

10.1 In the Scope section of the protocol, one goal of the study was described as "determine minimum time needed for structural disintegration /detachment in a simulated body environment." This goal was not achieved, since none of the samples showed loss of mechanical integrity during the 180 days of the study. The fact that none of the samples lost mechanical integrity is considered a favorable outcome, and a new study will not be conducted to learn the time needed for loss of mechanical integrity.

10.2 The protocol specified that the temperature of the water bath be checked at least once per week. However, the week of December 24, 2001, the water bath temperature was not checked. This minor deviation did not affect the results of the study.

10.3 The protocol says to ultrasonically clean the samples before and after SEM handling. None of the devices was cleaned after SEM imaging. This deviation had no affect on the study results.

10.4 The protocol requires two reports to be written: one at two months, and a final report with all six months of data. A three month report was written, rather than a two month report, because three months of data were submitted to the FDA in the PMA Module III: Biocompatibility. This deviation has no affect on the study results.

10.5 The pH of the six month saline samples was checked using pH test strips before the saline samples were sent out for metal leaching analysis.

Testing the pH was not part of the original protocol. This deviation does not affect the study results.

11.0 CONCLUSIONS

- The Essure Micro-insert passes the corrosion susceptibility bench test.
- The daily leaching rate of nickel and tin ions released are at least 2000 times less than everyday intake of food and water and exposure to environment.
- The daily leaching rate of chromium is below the detection limit.
- The Essure Micro-insert maintained mechanical integrity during the six months of exposure to a bench top corrosive saline environment.
- The corrosion rate of the solder is acceptably low.
- Besides the solder, no other signs of corrosion were visible in the SEM images.

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APPENDIX 1

APPENDIX 1

Table 3: Cumulative Simulated Environment (A Samples)

Sample #	Time in Saline (days)	Nickel (µg/day)	Chromium (µg/day)	Tin (µg/day)
A-1-a	7	0.03	<0.03	4.2
A-1-b	7	0.13	<0.03	23
A-1-c	7	0.057	<0.03	6.9
	Average per vial	*0.07*	*0.03*	*11*
A-2-a	14	0.066	<0.01	11
A-2-b	14	0.046	<0.01	17
A-2-c	14	0.063	<0.01	14
	Average per vial	*0.058*	*0.01*	*14*
A-3-a	30	0.007	<0.007	0.37
A-3-b	30	0.047	<0.007	8.9
A-3-c	30	0.016	<0.007	2.5
	Average per vial	*0.023*	*0.007*	*3.9*
A-4-a	60	0.005	<0.003	1.09
A-4-b	60	<0.003	<0.003	0.720
A-4-c	60	<0.003	<0.003	0.28
	Average per vial	*0.004*	*0.003*	*0.70*
A-5-a	90	<0.002	<0.002	0.098
A-5-b	90	<0.002	<0.002	0.20
A-5-c	90	<0.002	<0.002	0.20
	Average per vial	*0.002*	*0.002*	*0.17*
A-6-a	120	0.0033	<0.002	0.587
A-6-b	120	0.002	<0.002	0.23
A-6-c	120	0.002	<0.002	0.21
	Average per vial	*0.002*	*0.002*	*0.34*
A-7-a	180	0.0009	<0.001	0.12
A-7-b	180	0.0031	<0.001	0.13
A-7-c	180	0.0089	<0.001	0.258
	Average per vial	*0.0043*	*0.001*	*0.17*

The raw data is measured in (mg/L). To calculate the rate in (µg/day) the following equation was used:

$$rate(\mu g / L) = \frac{rate(mg / L) * (4ml) * (1000\mu g / mg)}{(1000ml / L) * (days\_in\_saline)}$$

The number of significant digits shown is the maximum number of significant digits possible based on the raw data.

APPENDIX 2

APPENDIX 2

Table 4: Disrupted Simulated Environment (B Samples)[4]

Sample #	Time Device in Saline (days)	Time Saline Tested (days)	Nickel (µg/day)	Chromium (µg/day)	Tin (µg/day)
B-1-a	7	7	0.097	<0.03	14
B-1-b	7	7	0.14	<0.03	20
B-1-c	7	7	0.13	<0.03	22
B-1-d	7	7	0.13	<0.03	27
B-1-e	7	7	0.10	<0.03	15
B-1-f	7	7	0.063	<0.03	7.4
Average per vial			*0.11*	*0.03*	*18*
B-2-a	14	7	<0.03	<0.03	15
B-2-b	14	7	<0.03	<0.03	16
B-2-c	14	7	<0.03	<0.03	15
B-2-d	14	7	<0.03	<0.03	20
B-2-e	14	7	<0.03	<0.03	17
B-2-f	14	7	<0.03	<0.03	20
Average per vial			*0.03*	*0.03*	*17*
B-3-a	30	16	<0.01	<0.01	3.3
B-3-b	30	16	<0.01	<0.01	0.50
B-3-c	30	16	<0.01	<0.01	0.90
B-3-d	30	16	<0.01	<0.01	0.45
B-3-e	30	16	<0.01	<0.01	0.88
B-3-f	30	16	<0.01	<0.01	1.5
Average per vial			*0.01*	*0.01*	*1.3*
B-4-a	60	30	<0.007	<0.007	0.40
B-4-b	60	30	<0.007	<0.007	0.16
B-4-c	60	30	<0.007	<0.007	0.23
B-4-d	60	30	<0.007	<0.007	0.43
B-4-e	60	30	<0.007	<0.007	0.64
B-4-f	60	30	<0.007	<0.007	0.36
Average per vial			*0.007*	*0.007*	*0.37*

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[4] Some of the data for the disruptive samples that were reported to the FDA in Table 2 of Appendix F of the June 21, 2002 response were in error. However, the true values are even lower than those that were erroneously reported. This table includes the corrected values.

Sample #	Time Device in Saline (days)	Time Saline Tested (days)	Nickel (µg/day)	Chromium (µg/day)	Tin (µg/day)
B-5-a	90	30	<0.007	<0.007	0.68
B-5-b	90	30	<0.007	<0.007	0.19
B-5-c	90	30	<0.007	<0.007	0.07
B-5-d	90	30	<0.007	<0.007	0.09
B-5-e	90	30	<0.007	<0.007	0.1
B-5-f	90	30	<0.007	<0.007	0.27
		Average per vial	*0.007*	*0.007*	*0.23*
B-6-a	120	30	<0.007	<0.007	0.092
B-6-b	120	30	<0.007	<0.007	0.044
B-6-c	120	30	<0.007	<0.007	<0.007
B-6-d	120	30	<0.007	<0.007	0.020
B-6-e	120	30	<0.007	<0.007	0.081
B-6-f	120	30	<0.007	<0.007	2.35
		Average per vial	*0.007*	*0.007*	*0.43*
B-7-a	180	60	0.002	<0.003	0.006
B-7-b	180	60	0.003	<0.003	0.003
B-7-c	180	60	0.001	<0.003	0.005
B-7-d	180	60	0.003	<0.003	0.003
B-7-e	180	60	0.003	<0.003	0.0093
B-7-f	180	60	0.002	<0.003	0.040
		Average per vial	0.002	0.003	0.011

The raw data is measured in (mg/L). To calculate the rate in (µg/day) the following equation was used:

$$rate(\mu g / L) = \frac{rate(mg / L) * (4ml) * (1000\mu g / mg)}{(1000ml / L) * (days\_saline\_tested)}$$

The number of significant digits shown is the maximum number of significant digits possible based on the raw data.

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APPENDIX 3

~~CHRI~~STIAN CORROSION STUDY
Lot# R0012700|

TRAVELER for
STOP, Sterile, 2-Device – 100959 (E1635)

Shop Order 1058
Traveler no. N/A
BPCS entry ☐

Process	Materials, BPCS #		Initial	Date	Qty Passed
1. Equipment Setup	N/A	N/A			
2. Line Clearance SOP00922 rev (E)	N/A	N/A	Gc	10/10/01	N/A
3. QA Verification of Line Clearance SOP00922 rev (E)	N/A	N/A	Gc HS	10/10/01 10/10/01	N/A N/A
4. Fiber R0667 rev (C)	Fiber 100913 Inner/Outer Coil Subassembly101029 70% Alcohol 100177	Lot no. 0168000150 / 0103000005 Lot no. RD 0127709 Lot no. 0105000057 Exp 1/31/02	TK HV	10/9/01 10/10/01	66 SEE NOTE
5. Wind Down R1695 rev ( ) E0685-03 rev ( )	Release Cath S/A 100828 Delivery Wire S/A 100798 CW Holder 100730 Set Screw 100793	Lot no. Lot no. Lot no. Lot no.			
6. Inspection I Q0685-03 rev ( ) VS1590 rev ( )	Inspection Notes:	Qty reworked:___ by___ on _/_/_			
7. Bend Tip R1502 rev ( )	N/A	N/A			
8. Handle I R1502 rev ( )	Delivery Cath S/A 100886 Loctite 4011 100496 Right Handle 100728 Rack 100726 Detent 100725 Thumbwheel 100724 Button 100723	Lot no. Lot no. exp Lot no. Lot no. Lot no. Lot no. Lot no.			
9. Inspection I Q0768 rev ( ) E0768 rev ( ) VS1534 rev ( )	Inspection Notes:	Qty reworked:___ by___ on _/_/_			
10. Handle II R1502 rev ( )	Left Handle 100727 S. S. Screws 100800	Lot no. Lot no.			
11. Inspection II Q0766 rev ( )	Inspection Notes:				
12. Package R1617 rev ( )	Single Tray S/A 101005 Pouch 100822 Sticker 100128	Lot no. Lot no. Lot no.			
13. Seal Pouches R0102 rev ( )	N/A	N/A			
14. Inspection II Q1624 rev ( )	Inspection Notes:	Qty reworked:___ by___ on _/_/_			

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RW

Additional Traveler Notes: FOUR ASSEMBLIES (101029) FROM SHOP ORDER 1107 WERE REJECTED BUT HAD THE FIBER PROCESS PERFORMED AS PART OF THIS SHOP ORDER FOR A TOTAL OF 70 DEVICES. 10/10/01

CONTROLLED DOCUMENT

10/10/01

Revision Level J	Conceptus CONFIDENTIAL Document QAF-1700 LHR for 100959 (E1635) – Traveler for STOP, Sterile 2-Device	Page 1 of 1

Lot History Record Review Form
QAF-00925

Part Number E0644-02 rev. C
Lot Number RD 0127710
Shop Order No. 1108-1

	PASS	FAIL
General	☐	☐
Inspection and Testing	☑	☐
Revision Levels	☑	☐
Raw Material Lot Numbers	☑	☐
Quantity	☑	☐
Comments	☑	☐

General
- Input fields are completed with correct information (signatures, initials, dates, quantities, data).
- All pages are present.

Inspection and Testing
- Verify that inspections were performed at the correct sample size.
- Verify samples have passed any required testing.

Revision Levels
- Revision levels of all documents used are recorded.
- Verify that revisions recorded are appropriate for build dates.

Raw Material Lot Numbers
- All Raw Material lots used have been recorded.
- Raw Material lots are released prior to LHR closure.
- Raw Material lots have not expired.

Quantity
- Are changes in quantity reasonable?
- Quantities cannot increase without justification.

Comments
- Comments must be signed and dated.
- Review all comments recorded on the front and back of the LHR.
- Verify that comments make sense and resulting actions are appropriate.
- If comments refer to material being rejected, were units rejected?

Addition requirements for Finished Goods or Top Assemblies N/A ☑ PASS ☐ FAIL ☐
- Verify that Subassembly lots are released prior to LHR closure.
- Sterilization Date YEAR ______ MONTH ______ DAY ______ (List the date Aeration is complete). Sterile Load SL-______
- Expiration Date YEAR ______ MONTH ______ DAY ______ (Required for Sterile Labeled Finished Goods)

Step	Discrepancy	Resolved by	Date	Comments
8-15	Line clearance not performed	CL/KY	12/18/01	R&D accepts lot "as is", see MM note to CL (12/12/01) regarding purpose of lot

If applicable, the following must be completed:

Red-lines to an ECO-controlled process require a completed ECO prior to LHR release. Attach the ECO cover page for reference.

List document numbers and new rev level. ______

MRRs or QAIs must be dispositioned prior to LHR release. Any unusual observations noted were investigated via MRR or QAI. Attach verification.

List MRR or QAI numbers 801

QUANTITY DISPOSITIONED 70

Disposition Assigned:
- ☑ Approved
- ☐ Rejected
- ☐ Other ______

If Rejected, designate one or more follow-up actions
- ☐ Rework
- ☐ Scrap
- ☐ Non-Human Use Only

REVIEWED BY ______ DATE 12-18-01
Operations

Doc Control PW

DISPOSITIONED BY Kirk (YOUNG) DATE 12/18/01
Quality Engineer or Designee

QAF-00925 Rev. H (Refer to SOP-00921)

MEMO

Date: 12/12/01
To: C. Lowe
From: M. Martinez M. Martz 12/12/01
Re: Etched units used for corrosion test.

The following describes the process and inspections performed on etched outer coils used for VP-0191.PV Rev 1

1. Three lots of etched outer coils were produced. These Lots were entitled Lots A, B and C. The LHR's used to produce Etched Coils from Lots A,B, and C are attached to this memo. Only steps 4 through 6 were performed per the QAF-1701 rev E, Outer coil subassembly. All raw materials are recorded on these LHR's.
2. The etching process was performed on all three lots following the attached redline Oxide Removal work instruction R0704, and attached redline Work instruction Acid Preparation R1727.
3. Inspection of coils were performed per attached redlined, inspection was performed by QA. The lots were identified by the Test group A and B, followed by Lot group A,B, or C.
4. 80 coils were handed to Manufacturing for use in engineering build for Corrosion testing. These 80 coils were randomly pulled from all three of the lots A, B, C. No other process or manipulation was performed on the coils before the transfer.

Doc Control
PW

VR 0191

Attribute Data Sheet

Sample	Pass	Fail	Comments
1		X	oxidation
2	X		
3	X		
4	X		
5	X		
6	X		
7	X		
8	X		
9	X		
10	X		
11	X		
12	X		
13	X		
14	X		
15	X		
16	X		
17	X		
18	X		
19	X		
20	X		
21	X		
22	X		
23	X		
24	X		
25	X		
26			
27			
28	n/A		
29			
30		HI 9/21/01	
31			
32			
33			
34			
35			
36			
37			
38			
39			
40			

Date: 9-21-01

Performed By: H SINGH

Group: A-A

VR 0191

Doc Control PW

N/A [illegible] 12/12/01

Attribute Data Sheet

Sample	Pass	Fail	Comments
1	X		
2	X		
3	X		
4	X		
5	X		
6	X		
7	X		
8	X		
9	X		
10	X		
11	X		
12	X		
13	X		
14	X		
15	X		
16	X		
17	X		
18	X		
19	X		
20	X		
21	X		
22	X		
23	X		
24	X		
25	X		
26			
27			
28			
29			
30			
31			
32			
33			
34			
35			
36			
37			
38			
39			
40			

N/A HS 9/21/01

Date: 9-21-01

Performed By: H SINGH

Group: A - B

VR 0191

Doc Control PW

N/A 12/12/01

Attribute Data Sheet

Sample	Pass	Fail	Comments
1	X		
2	X		
3	X		
4	X		
5	X		
6	X		
7	X		
8	X		
9	X		
10	X		
11	X		
12	X		
13	X		
14	X		
15	X		
16	X		
17	X		
18	X		
19	X		
20	X		
21	X		
22	X		
23	X		
24	X		
25	X		
26			
27			
28			
29			
30			
31	N/A	HS 9/21/01	
32			
33			
34			
35			
36			
37			
38			
39			
40			

Date: 9-21-01

Performed By: H SINGH

Group: A-C

VR 0191

Doc Control

N/A MA 12/12/01

Attribute Data Sheet

Sample	Pass	Fail	Comments
1	X		
2	X		
3	X		
4	X		
5	X		
6	X		
7	X		
8	X		
9	X		
10	X		
11	X		
12	X		
13	X		
14	X		
15	X		
16	X		
17	X		
18	X	N/A	HS 9-28-01
19	X		
20	X		
21	X		
22	X		
23	X		
24	X		
25	X		
26			
27			
28			
29			
30			
31			
32			
33			
34			
35			
36			
37			
38			
39			
40			

Date: 9-28-01

Performed By: H SINGH

Group: B-A

VR 0191

Doc Control PW

N/A MW 12/12/01

Attribute Data Sheet

Sample	Pass	Fail	Comments
1	X		
2	X		
3	X		
4	X		
5	X		
6	X		
7	X		
8	X		
9	X		
10	X		
11	X		
12	X		
13	X		
14	X		
15	X		
16	X		
17	X		
18	X		
19	X		
20	X	N/A	
21	X	HS 9/28/01	
22	X		
23	X		
24	X		
25	X		
26			
27			
28			
29			
30			
31			
32			
33			
34			
35			
36			
37			
38			
39			
40			

Date: 9-28-01

Performed By: H SINGH

Group: B-B

VR 0191

Doc Control
PW

N/A MW 12/12/01

Attribute Data Sheet

Sample	Pass	Fail	Comments
1	X		
2	X		
3	X		
4	X		
5	X		
6	X		
7	X		
8	X		
9	X		
10	X		
11	X		
12	X		
13	X		
14	X		
15	X		
16	X		
17	X		
18	X		
19	X		
20	X	N/A	
21	X	HS	
22	X	9/28/01	
23	X		
24	X		
25	X		
26			
27			
28			
29			
30			
31			
32			
33			
34			
35			
36			
37			
38			
39			
40			

Date: 9-28-01

Performed By: H SINGH

Group: B-C

Doc Control
PW

VR 0191

N/A HH 12/12/01

Conceptus

BPCS ☐
SFO 650
INV 100 ☐

Outer Coil Subassembly
QAF-1701, Lot History Record for 100795 (E0644-02)

Shop Order ________ Batch Number ________ Lot Number LOT C

Process	Material	Lot No.	Initial	Date	Qty Passed
1. Equipment Setup	E0578-02 Mandrel Bead 100936	Lot no.________			N/A
2. Line Clearance SOP00922 rev( )	N/A	N/A			N/A
3. QA Verification of Line Clearance SOP00922 rev( )	N/A	N/A			N/A
4. Wind, Anneal R1526 rev (F) E1524 rev (J)	E0482-04 NiTi Ribbon 100776	Lot no. 0102000046 Performed By Ross	MM RC	9/5/01 9/5/01	N/A
5. Trim, Inspect Q1524 rev (C) VS1554 rev (C)	Inspection Notes:	Spool B	RC	9/5/01	
6. Etch Coils R1727 rev ( ) R0704 rev ( )	Hydrogen Peroxide 100810 70% IPA 100177 Etching Concentrate 100809 Deionized Water 100798 Alconox Powder 100762 Sodium Bicarbonate 100932	Lot no. 0106000067 exp____ Lot no 0105000057 exp 11/31/01 Lot no. 0106000048 exp 6/1/01 Lot no. 0108000129 exp 10/31/01 Lot no. 0100000058 Lot no. 0105000019	RC C.S. MM CR	9/11/01 9/11/01 9/11/01	
7. Inspect Etching Q1718 rev ( )	Inspection Notes: MM 9/14/01				
8. Make Bump R1501 rev ( )	E0700-05 Wire for Bump 100915 Lot no.____ MM 9/14/01				as needed
9. Weld Bump R0701 rev ( )	E0503-11 Band, Platinum 100777	Lot no. 0108000067	JC JA.	9/13/01	
10. Stage Sandwich R0702 rev (E)	E0503-12 Ring, Platinum 100814	Lot no. 0108000014	JC JA.	9/13/01	
11. Weld Sandwich R0702 rev (E)	N/A	N/A	JA	9/13/01	
12. Inspect Outer Coil E0644-02 rev ( ) Q0644 rev ( )	Inspection Notes:				
13. Cycle Test R0735 rev ( )	Inspection Notes: MM 9/14/01				Doc Control DN
14. Outer Coils removed for additional testing		Qty removed for testing________			Qty remaining

Additional Comments: (Record step number if comments are related to a particular step.)

Conceptus

BPCS
SFC 650 ☐
INV 130 ☐

Outer Coil Subassembly
QAF-1701, Lot History Record for 100795 (E0644-02)

Shop Order ________ Batch Number ________ Lot Number LOT B

Process	Material	Lot No.	Initial	Date	Qty. Passed
1. Equipment Setup	E0678-02 Mandrel Bead 100936	Lot no.________			N/A
2. Line Clearance SOP00922 rev( )	N/A	N/A			N/A
3. QA Verification of Line Clearance SOP00922 rev( )	Appendix 14 N/A	N/A		mm	N/A
4. Wind, Anneal See R1526 rev (F) E1524 rev (U)	E0482-04 NiTi Ribbon 100776 Appendix	Lot no. 0103000045 PERFORMED BY Ross	mm RC	9/5/01 9/5/01	or N/A
5. Trim, Inspect See Appendix Q1524 rev (E) 9/7/01 RC VS1584 rev (G) 9/5/01 RC	Inspection Notes:		RC	9/8/01	
6. Etch Coils R1727 rev ( ) R0704 rev ( )	Hydrogen Peroxide 100810 70% IPA 100177 Etching Concentrate 100809 Deionized Water 100798 Alconox Powder 100762 Sodium Bicarbonate 100932	Lot no. 0106000067 exp 1/31/05 Lot no. 0105000057 exp 1/31/04 Lot no. 0106000048 exp 6/1/02 Lot no. 0108000179 exp 10/31/02 Lot no. 0105000058 Lot no. 0105000019	RC C.S. CR mm	9/11/01 9/11/01 9/11/01	
7. Inspect Etching Q1718 rev ( )	Inspection Notes: mm 9/11/01				
8. Make Bump R1501 rev ( )	E0700-05 Wire for Bump 100815 mm 9/12/01	Lot no.________		9/13/01	As needed
9. Weld Bump ~~R0701 rev ( )~~	~~E0503-11 Band, Platinum 100777~~	Lot no. 0108000062 ~~0103000045~~ mm 9/5/01	JA AC	9/13/01	
10. Stage Sandwich R0702 rev (E)	E0503-12 Ring, Platinum 100814	Lot no. 0108000014	AC JA.	9/13/01	
11. Weld Sandwich R0702 rev (E)	N/A	N/A	JA.	9/13/01	
~~12.~~ Inspect Outer Coil ~~E0644-02 rev ( )~~ Q0844 rev ( )	Inspection Notes:				
13. Cycle Test R0735 rev ( )	Inspection Notes: mm 9/14/01				
14. Outer Coils removed for additional testing	Qty removed for testing________				Qty remaining

Additional Comments: (Record step number if comments are related to a particular step.)

Doc Control
PW

VR 0191

Revision E	Conceptus CONFIDENTIAL Document QAF-1701 LHR for 100795 (E0644-02) – Outer Coil Subassembly	Page 1 of 1

Conceptus

BPOS ☐
SFC 550
INV 130 ☐

Outer Coil Subassembly
QAF-1701, Lot History Record for 100795 (E0644-02)

Shop Order ______ **Batch Number** ______ **Lot Number** Lot A

Process	Material	Lot No.	Initial	Date	Qty Passed
1. Equipment Setup	E0678-02 Mandrel Bead 100938	Lot no.______			N/A
2. Line Clearance SOP00922 rev( )	N/A	N/A			N/A
3. QA Verification of Line Clearance SOP00922 rev( )	N/A	N/A			N/A
4. Wind, Anneal R1526 rev (F) E1524 rev (J) SEE Appendix F APP mu 9/5/01	E0492-04 NiTi Ribbon 100776	Lot no. 0102000046 PERFORMED BY ROSS	mu RC	9/5/01 9/5/01	N/A
5. Trim, Inspect Q1524 rev (C) VS1554 rev (C) See Appendix mu 9/5/01	Inspection Notes:	SP0047	RC	9/5/01	
6. Etch Coils R1727 rev ( ) R0704 rev ( )	Hydrogen Peroxide 100810 70% IPA 100177 Etching Concentrate 100809 Deionized Water 100798 Alconox Powder 100762 Sodium Bicarbonate 100932	Lot no. 0106000067 exp 1/31/03 Lot no. 0105000057 exp 1/31/04 Lot no. 0106000048 exp 6/1/02 Lot no. 0109000125 exp 10/31/02 Lot no. 0105000058 Lot no. 0105000019	CR C.S. 9/11/01 mu CS RC	9/11/01 9/11/01 9/11/01	
7. Inspect Etching Q1718 rev ( )	Inspection Notes: mu 9/11/01				
8. Make Bump R1501 rev ( )	E0700-05 Wire for Bump 100816 Lot no. mu 9/11/01 Not nd.				as needed
9. Weld Bump R0701 rev ( )	E0503-11 Band, Platinum 100777	Lot no. 0108000067	RC JA.	9/13/01	
10. Stage Sandwich R0702 rev (E)	E0503-12 Ring, Platinum 100814	Lot no. 0108000014	RC JA.	9/13/01	
11. Weld Sandwich R0702 rev (E)	N/A	N/A	JA.	9/13/01	
12. Inspect Outer Coil E0644-02 rev ( ) Q0544 rev ( )	Inspection Notes:				
13. Cycle Test R0735 rev ( )	Inspection Notes: mu 9/11/01				
14. Outer Coils removed for additional testing	Qty removed for testing______				Qty remaining

Additional Comments: (Record step number if comments are related to a particular step.)

VR 0191

Doc Control
DW

Conceptus

WORK INSTRUCTION ACID PREPARATION

R1727

Revision Level	ECO#	Effective Date	Originators Name/ Signature/Date	Change Request
A	3641	07/18/01	M. Martinez	Initial Release. Acid Solution preparation, removed from R0704.
B	3783	08/21/01	M. Martinez	Add using pyrex dish for solution prep.

Redlined
Document
M. Martinez 12/12/07.

VR 0191

Doc Control
PW

1.0 PURPOSE:

This procedure defines the work instruction for preparing the acid solution for etching the annealed outer coil.

2.0 DOCUMENTS:

2.1 As specified on device specific DMR.

3.0 PRODUCTION PARTS:

3.1 As specified on device specific DMR.

4.0 EQUIPMENT

4.1	Hot Plate with magnetic stirring mechanism	FA90604 or FA90677
4.2	Ultrasonic Cleaner	

5.0 MATERIALS

5.1	Detergent	E0071-01
5.2	De-ionized Water	E0075
5.3	Etching Concentrate, ESTER-07	E0706
5.4	Hydrogen Peroxide, 30%	E0707
5.5	Isopropyl Alcohol, 70%	E0074
5.6	Sodium Bicarbonate	E1598

6.0 TOOLS/SUPPLIES

6.1	Latex or nitrile gloves	
6.2	Safety glasses or goggles	
6.3	Lab coat or chemical resistant apron	
6.4	Plastic, Graduated cylinder	
6.5	Syringe or pipette	
6.6	Wire basket for Ultrasonic Bath	
6.7	Tweezers	
6.8	Lint free wipes	
6.9	Vials	
6.10	Pyrex Dish 190x100 No. 3140	
6.11	Thermometer or Temperature Probe	FA90676
6.12	600g Scale	FA90642
6.13	1" Magnetic stirrer	
6.14	Glass, Graduated Cylinder 25 ml	
6.15	Glass, Graduated Cylinder 100ml	
6.16	Glass, Beaker 100 ml	
6.17	Glass, Beaker 1000 ml	
6.18	Glass, Beaker 400 ml	

7.0 Procedure

7.1 All glass ware is to be cleaned with detergent (E0071-01), prior to production.

7.2 Rinse glassware with De-ionized water (E0075).

7.3 **Wear waterproof gloves, eye protection, and a lab coat or apron during solution preparation and use.**

Doc Control
PW

VR 0191

DEIONIZED WATER (E0075)

7.4 Place a dry, clean 100 (ml) graduated cylinder on the scale.

7.5 Zero out the scale.

7.6 Pour De-ionized water into the graduated cylinder until the digital readout is 181 ± 1g.

7.7 Pour De-ionized water into a 1000 (ml) glass beaker or Pyrex Glass Dish 190x100 No. 3140.

7.8 Pour excess water into a waste container.

ETCHING CONCENTRATE (E0706)

Note: Keep etching concentrate at/or above room temperature.

7.9 Mix the Etching concentrate ESTER-07 (E0706) by swirling the contents.

7.10 Place a dry, clean, 100 (ml) graduated cylinder on the scale.

7.11 Zero out the scale.

7.12 Pour etching concentrate into the graduated cylinder until the digital readout is 272 ± 1(g).

7.13 Pour etching concentrate inwith the De-ionized water.

7.14 Pour excess solution into Acid waste Container.

HYDROGEN PEROXIDE (E0707)

7.15 Carefully loosen the cap of the HYDROGEN PEROXIDE, 30% (E0707).

7.16 Place a dry, clean 100 (ml) graduated cylinder on the scale.

7.17 Zero out the scale.

7.18 Pour hydrogen peroxide into the 100 (ml) beaker until the digital readout is 45 ± 1 (g).

7.19 Pour the hydrogen peroxide inwith De-ionized water and etching concentrate.

7.20 Pour excess peroxide into Acid Waste Container

ACID SOLUTION

7.21 Mix the etching solution with a stirring rod.

7.22 Pour 68ml ± 3ml of the etching solution into the 100 ml graduated cylinder or 100 ml beaker.

7.23 Label 100 (ml) graduated cylinder Reserve Acid.

7.24 Pour the remaining solution into Pyrex Glass Dish 190x100 No. 3140.

7.25 Place dish on hot plate.

7.26 Set the magnetic stirrer to 150 RPM.

7.27 Place 1" magnetic stirrer in acid solution.

7.28 ~~Place the temperature probe into acid solution.~~

7.29 ~~Set hot plate temperature to 60°C ± 2°C.~~

7.30 ~~Heat acid solution for approximately 30 minutes.~~

4/4/01

Doc Control
PW

VR 0191

SODIUM BICARBONATE (E1598)

7.31 Mix ½ a spoonful of bicarbonate in a beaker with 300 (ml) of De-ionized water.

9.0 INSPECTION CRITERIA:

9.1 N/A

10.0 SHUT DOWN/CLEAN UP.

10.1 Turn off the hot plate.

10.2 Turn off the ultra sonic cleaner.

11.0 TRAINING.

11.1 Training must be performed by a process expert.

11.2 Personnel being trained must be able to produce 2 complete batches of acid solution and accompanying solutions.

5/4/01

Conceptus

WORK INSTRUCTION-OXIDE REMOVAL

R0704

Revision Level	ECO#	Effective Date	Originators Name/ Signature/Date	Change Request
A	2905	8/23/00	Andrew Ortega	Update with new equipment (scale, stir plate, glassware); changed solution measurement from milliliters to grams.
B	2966	9/27/00	Andrew Ortega	Update etching lapse time from 24 hrs to 7 days. Specified orientation of fixtures in beaker.
C	3152	12/14/00	Andrew Ortega	Changed Etching solution; increased temp from 30 – 40C to 60C; add neutralizer and 2 stage rinse; etch proximal end first.
D	3318	03/22/01	Andrew Ortega	Add neutralize and rinse during 10 minute etching time. Added one time 20 minute ultrasonic clean, was 30 min on each side separately.
E	3397	04/25/01	M. Martinez	Add Training, inspection criteria, shut down. Clean document up. Update document to reference wound outer coil (E1524) instead of outer coil sub-assembly gamma device (E1524)
F	3427	05/02/01	M. Martinez	Increase ultrasonic rinse time in water for oxide removal. Add coil rework.
G	3640	07/18/01	M. Martinez	Rewrite document. Acid solution preparation removed to new Document R1727
H		MM 9/27/01	M. Martinez	Add new process window and instructions per VP-0167.

Doc Control PW

VR 0191

Reline

1.0 PURPOSE:

This procedure defines the work instruction for removing the Titanium Oxide from the Annealed Outer Coil Surface. E1524

2.0 DOCUMENTS:

2.1 As specified on device specific DMR.

3.0 PRODUCTION PARTS:

3.1 As specified on device specific DMR.

4.0 EQUIPMENT

4.1	Ultrasonic Cleaner	
4.2	Etching Fixture	E0772
4.3	Pyrex Dish 190x100 No. 3140	(For etching solution)
4.4	Thermometer or Temperature Probe	FA90676
4.5	Hot Plate with magnetic stirring mechanism	FA90604 or FA90677
4.6	1" Magnetic stirrer	
4.7	Glass, Graduated Cylinder 25 ml	
4.8	Glass, Graduated Cylinder 100ml	
4.9	Glass, Beaker 100 ml	
4.10	Glass, Beaker 1000 ml	
4.11	Glass, Beaker 400 ml	

5.0 MATERIALS

5.1	De-Ionized Water	E0075
5.2	Etching Concentrate, ETSER-07	E0706
5.3	Hydrogen Peroxide, 30%	E0707
5.4	Isopropyl Alcohol, 70%	E0074
5.5	Sodium Bicarbonate	E1598

6.0 TOOLS/SUPPLIES

6.1 Water proof gloves
6.2 Safety glasses or goggles
6.3 Lab coat or chemical resistant apron
6.4 Plastic, Graduated cylinder
6.5 Syringe or pipette
6.6 Wire basket for Ultrasonic Bath
6.7 Tweezers
6.8 Lint free wipes
6.9 Vials

8.0 PROCEDURE

FIXTURE PREPARATION (E0772):

NOTE: The subassembly quantity is limited to a maximum of 25 assemblies per fixture. A maximum of 5 fixtures may be used in the solution at any given time.

8.1 Position the proximal end of the outer coil subassemblies on the same side of etching fixture.

8.2 Verify that the proximal tip of the outer coil is touching the end of the fixture.

8.3 Position Delrin clip between the press to fit pins.

8.4 Press clip down.

CLEAN COILS 70% IPA (E0074):

8.5 Transfer 400 (ml) of 70% IPA into a 1000 (ml) beaker.

8.6 Place fixtures into beaker.

8.7 Orient the fixture(s) so that the subassemblies are horizontal in beaker.

8.8 Place Beaker in ultra sonic cleaner.

8.9 Set timer to 5 minutes.

8.10 Start timer.

8.11 Remove the fixture(s) and subassemblies from the Isopropyl Alcohol.

8.12 Allow components to air-dry for a minimum of 2 minutes.

8.13 Remove clip from the etching fixture and reposition the tip of the coils to touch fixture.

8.14 Reposition clip.

8.15 Using a microscope verify that the coils are straight and touch the tip of the etching fixture.

ETCHING:

Proximal Tip (short side):

8.16 Set timer to 22'(min.) 30"(sec.).

8.17 Place fixtures in etching solution.

8.18 Start timer.

8.19 Dip plastic ruler into solution.

8.20 Verify that the solution level is within 1.5 ± .1 (cm).

8.21 If required fill solution level to specified height.

8.22 Remove fixtures after timer has signaled the end of process.

8.23 Submerge entire fixture in neutralizer for a minimum of 15 seconds.

8.24 Submerge entire fixture in beaker number 1 (300 (ml) De-ionized water), for a minimum of 15 seconds.

8.25 Submerge entire fixture in beaker number 2 (300 (ml) De-ionized water), for a minimum of 15 seconds.

8.26 Remove clip from the etching fixture and reposition the tip of the coils to touch fixture.

8.27 Reposition clip.

8.28 Using a microscope verify that the coils are straight and touch the tip of the etching fixture.

8.29 Set timer to 22'(min.) 30"(sec.).

8.30 Place fixtures in etching solution.

VR 0191

8.31 Start timer.

8.32 Dip plastic ruler into solution.

8.33 Verify that the solution level is within 1.5 ± .1 (cm).

8.34 If required fill solution level to specified height.

8.35 Remove fixtures after timer has signaled the end of process.

8.36 Submerge entire fixture in neutralizer for a minimum of 15 seconds.

8.37 Submerge entire fixture in beaker number 1 (300 (ml) De-ionized water), for a minimum of 15 seconds.

8.38 Submerge entire fixture in beaker number 2 (300 (ml) De-ionized water), for a minimum of 15 seconds.

8.39 Remove fixtures from the etching solution.

Distal Tip (Long Side):

8.40 Remove the clip from the etching fixture and position the Distal tip of the coils to touch fixture.

8.41 Reposition clip.

8.42 Using a microscope verify that the coils are straight and touch the tip of the etching fixture.

8.43 If volume is below 1.5 ±.1 (cm), refill to specified level.

8.44 Set timer to 22'(min.) 30"(sec.).

8.45 Place fixtures in etching solution.

8.46 Start timer.

8.47 Dip plastic ruler into solution.

8.48 Verify that the solution level is within 1.5 ± .1 (cm).

8.49 If required fill solution level to specified height.

8.50 Remove fixtures after timer has signaled the end of process.

8.51 Submerge entire fixture in neutralizer for a minimum of 15 seconds.

8.52 Submerge entire fixture in beaker number 1 (300 (ml) De-ionized water), for a minimum of 15 seconds.

8.53 Submerge entire fixture in beaker number 2 (300 (ml) De-ionized water), for a minimum of 15 seconds.

8.54 Remove clip from the etching fixture and reposition the tip of the coils to touch fixture.

8.55 Reposition clip.

8.56 Using a microscope verify that the coils are straight and touch the tip of the etching fixture.

8.57 Set timer to 22'(min.) 30"(sec.).

8.58 Place fixtures in etching solution.

8.59 Start timer.

8.60 Dip plastic ruler into solution.

8.61 Verify that the solution level is within 1.5 ± .1 (cm).

8.62 If required fill solution level to specified height.

8.63 Remove fixtures after timer has signaled the end of process.

VR 0191

8.64 Submerge entire fixture in neutralizer for a minimum of 15 seconds.

8.65 Submerge entire fixture in beaker number 1 (300 (ml) De-ionized water), for a minimum of 15 seconds.

8.66 Submerge entire fixture in beaker number 2 (300 (ml) De-ionized water), for a minimum of 15 seconds.

8.67 Remove fixtures from the etching solution.

ULTRA-SONIC CLEANING DI WATER

8.68 Set timer to a minimum of 90 minutes.

8:69 Place fixtures in the ultra sonic water bath.

NOTE: Use fresh water in the ultra sonic cleaner.

8.70 Transfer the fixtures to 400ml beaker(s) filled with de-ionized water (E0075).

8.71 Fill the ultrasonic cleaner to the operational level with water as indicated on the bath.

8.72 Place beaker(s) into the wire mesh basket of the ultrasonic cleaner.

8.73 Start timer.

8.74 Remove fixtures after alarm has signaled.

ULTRA-SONIC CLEANING 70% IPA

8.75 Transfer fixtures to 400 (ml) beaker(s) of 70% IPA.

8.76 Set timer for 2 minutes.

8.77 Orient the fixture(s) so that the subassemblies are horizontal in beaker.

8.78 Place beakers in ultra sonic cleaner.

8.79 Start Timer.

8.80 Remove fixtures from IPA after alarm signals.

8.81 Place device components on lint free cloth.

8.82 Allow components to dry for a minimum of 2 minutes.

8.83 Place the outer coils into plastic vials.

8.84 Record the time and date etching was completed on the build document.

WASTE DISPOSAL

8.85 Dispose of all solution after one complete cycle.

8.86 Pour waste solution in ETSER-07 Waste Container.

8.87 Pour waste de-ionized water in sink.

8.88 Pour waste IPA in Waste Container.

8.89 Clean all equipment with detergent.

8.90 Rinse and allow to air dry.

VR 0191

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9.0 INSPECTION CRITERIA:

9.1 Inspect both distal and proximal ends of outer coils for etching. Reject if the coil is not etched a minimum of 1 mm.

9.2 There must be no oxide either proximal or distal located along the first mm of the coil.

9.3 Light oxide may be present from 1 mm UP TO SEVEN COILS.

10.0 SHUT DOWN.

10.1 Turn off the hot plate.

10.2 Turn off the ultra sonic cleaner.

10.3 Remove water form ultra sonic cleaner.

11.0 TRAINING.

11.1 Training must be performed by a process expert.

11.2 Personnel being trained must produce 50 etched outer coils before being allowed to manufacture production assemblies.

11.3 Units assembled for training, must be inspected by the designated process expert and pass the specification.

VR 0191

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PW

INSPECTION INSTRUCTIONS, ETCHING

1.0 TOOLS AND EQUIPMENT

1.1 Microscope
1.2 Tweezers

2.0 INSPECTION:

NOTE: INSPECTION TO BE PERFORMED USING A 10X MICROSCOPE

4.1 Inspect the proximal and distal tip of the outer coil, all oxide and flakes must be completely removed a minimum of 1mm, see Figure 1.

4.2 One millimeter from the proximal and distal tip, etching is acceptable within the first 7 coils, see Figure 1 and Figure 4.

4.3 Silver streaks located in the etched areas is acceptable, see Figure 2.

4.4 Spotting or longitudinal streaks located in the etched areas are acceptable, see Figure 1, 3, and 4.

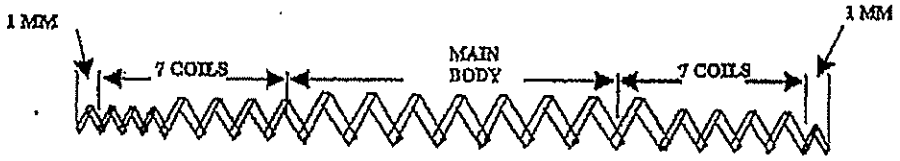
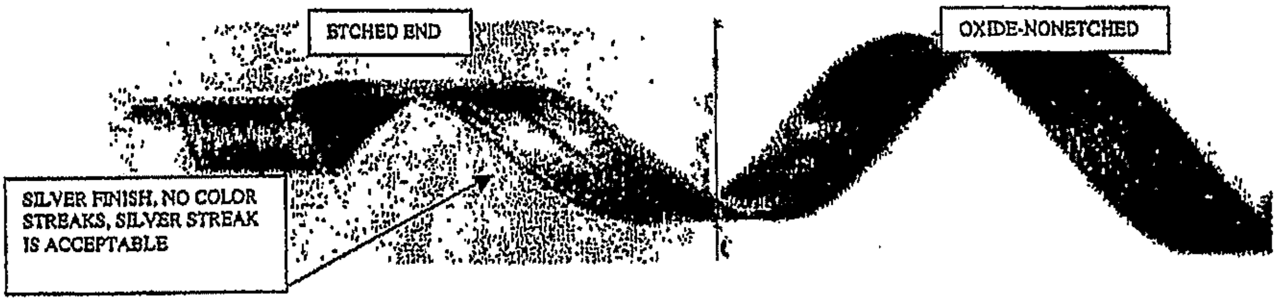


FIGURE 1 – DEFINITION OF PARTS OF THE COIL

N/A 12/12/01

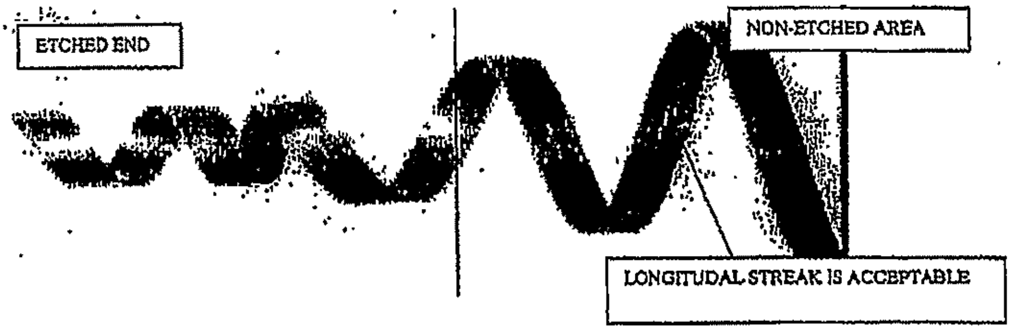


ETCHED END

OXIDE-NONETCHED

SILVER FINISH, NO COLOR STREAKS, SILVER STREAK IS ACCEPTABLE

Figure 2– ETCHED PROXIMAL OUTER COIL.

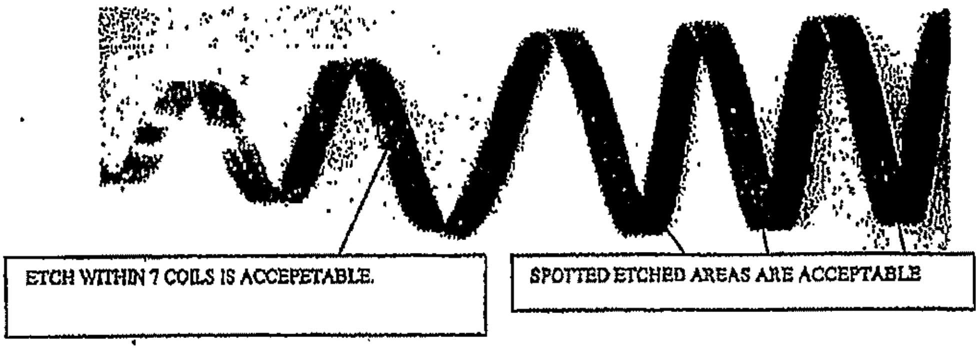


ETCHED END

NON-ETCHED AREA

LONGITUDAL STREAK IS ACCEPTABLE

Figure 3– ETCHED DISTAL END OF OUTER COIL.



ETCH WITHIN 7 COILS IS ACCEPETABLE.

SPOTTED ETCHED AREAS ARE ACCEPTABLE

Figure 4 -LIGHT ETCH and SPOTTED ETCH IN THE MAIN BODY OF THE COIL.

MM 12/12/01

APPENDIX 4

Notebook No. 257

PROJECT Corrosion Test - Water Bath Set-up + Monitoring Continued From Page

Corrosion Susceptibility Test Protocol on Conceptus Essure
pbc device VR0191 pv rev 1

Equipment used:
~~water bath VWR model 1235 PMI 0157~~ This water bath
~~calibration done 5-31-01 calibration due 11-30-01~~ not used
CS 11-19-01

Fluke 52II Thermometer ID # FA90694
Calibration Done 3-22-01/ Calibration Due 3-22-02/3-10-03
3-10-02

D.I. Water Lot# 0110000197

Water Bath setup: water bath VWR model 1240 S/N 1007388

10-8-01
Bath was filled with tap water to a depth of 1½". Bath temperature was set to 37°C + covered. The temperature was monitored for 4 days.

10-12-01 8:30 AM
The water bath was emptied + refilled with DI water to a depth of 1¼". The temperature was set at 32°C
At 12:30 the corrosion samples were placed in the bath, the temperature was 37.1°C at the bottom of the bath and 36.8°C at the top of the water level. The temperature was taken in the center of the tank.

Solution Preparation:
Sodium Chloride .85-.90% Lot # RA0048405T Exp Date 5-31-02
Buffer Solution Ph 7.00 Lot # ~~RA[illegible]~~ CS 11-19-01
RA0128401

Mixed 150 ml of Sodium chloride + 30 drops of buffer solution in a 200 ml beaker. The ph was tested with indicator strips, drops of buffer solution were added until the Ph was between 6+7 ph.

Continued on Page 65.

Read and Understood By VR 0191

Doc Control PW

11-19-01 Date 1-11-02
Signed Date Signed Date

PROJECT Corrosion Test water bath set-up & monitoring

Notebook No. 239

Continued From Page 64

Date	Time	Temp °C
10-8	8:30	26.2°C
10-8	2:30	37.6/37.6
10-9	2:30	37.4/37.5
10-10	9:00	36.5/36.4
10-10	3:30	36.1/36.1
10-11	8:00	36.9/37.0
10-11	4:30	37.4/37.4
10-12	12:50	37.0/36.8
10-12	4:30	37.4/37.6
10-15	8:00	36.9/36.9
10-16	8:30	36.8/36.8
10-17	8:00	36.9/36.9
10-18	10:30	37.3/37.3
10-19	11:30	36.8/36.8
10-22	7:30	37.4/37.4
10-23	9:00	37.1/37.2
10-24	9:00	37.3/37.4
10-25	2:15	36.8/37.1
10-26	7:30	36.3/36.4
10-29	9:00	36.9/36.9
10-31	8:00	36.8/36.8
11-2	8:00	37.2/37.1
11-5	8:00	37.3/37.4
11-7	10:00	36.9/37.0
11-12	11:30	37.3/37.3
11-20	9:30	37.6/37.3
11-24	11:30	36.9/37.0
12-5	2:30	37.3/37.4
12-11	1:00	37.0/37.0
12-18	2:10	37.5/37.6
1-3-02	10:40	37.2/37.2

Date	Time	Temp
1-10-02	2:30	37.6/37.8
1-17-02	10:15	37.8/37.6
1-23	9:30	37.2/37.3
1-30	8:30	37.3/37.4
2-6-02	1:30	36.5/36.7
2-13-02	8:30	36.8/36.9
2-20	9:30	37.1/37.2

2-22-02

Doc Control PW

V.R. 0191

Continued on Page 66

Read and Understood By

Signed: Chyl | Date: 2-22-02

Signed: Elisa Aldrid | Date: 2-22-02

PROJECT Corrosion Test Vial numbers + Test Dates

Notebook No. 601
Continued From Page 65

Corrosion Susceptibility Test Protocol on Conceptus Essure
pbo device VP0914AK Rev1

Objective: to Record vial numbers and dates that testing
was started + completed.

Procedure in Lab notebook # 248 pg 71 was followed when removing devices from the vials - group A, and when replacing vials with solution - group B.

Oct. 12, 2001

Group A - All of group A vials with samples were placed in the water bath - 21 vials total.

Group B Vials numbered B-1-a through B-1-f were placed in the water bath.

Oct 19, 2001

Group A - vials numbered A-1-a, A-1-b, A-1-c were Removed.

Group B - Devices from vials numbered B-1-a thru B-1-f were Removed + placed into vials with solution numbered B-2-a thru B-2-f, then placed back in the water bath.

Continued on Page 67

Read and Understood By

10-19-01
Signed
Date

Elsa Aldridge
6-25-2002
Signed
Date

Oct 26, 2001.
~~Nov 12, 2001~~
C.S. 11-12-01

Group A - vials numbered A-2-a, A-2-b, A-2-c were removed

Group B - Devices from vials numbered B-2-a thru B-2-F were removed + placed into vials with solution numbered B-3-a thru B-3-F, then placed back in the water baths

Nov 12, 2001

Group A - vials numbered A-3-a, A-3-b, A-3-c were removed

Group B - Devices from vials numbered B-3-A thru B-3-f were removed and placed into vials with solution numbered B-4-a thru B-4-F, then placed back in the water bath.

Dec 11 2001

Group A - vials numbered A-4-a, A-4-b, A-4-c, were removed

Group B - Devices from vials numbered B-4-A thru B-4-f were removed and placed into vials with solution numbered B-5-a thru B-5-F then placed back in the water bath.

JAN 10, 2002

Group A - vials numbered A-5-a A-5-b, A-5-c were removed

Group B - Devices from vials numbered B-5-A thru B-5-f were removed + placed into vials with solution numbered B-6-A thru B-6-F then placed back into the water bath.

Continued on Page 68

Read and Understood By R

Chyl J	1-10-02	Elsa Aldridge	6-25-2002
Signed	Date	Signed	Date

PROJECT Corrosion Test Vial Numbers + Test Dates

Notebook No. 239
Continued From Page 67

Feb 11, 2002

Group A - Vials numbered A-6-A, A-6-B, A-6-C were Removed

Group B - Devices from vials numbered B-6-A thru B-6-F were Removed + placed into vials with solution numbered B-7-A thru B-7-F then placed back into the water bath

Water bath Monitoring Table continued from pg 65

Date	Time	Temp °C
2-27-02	2:30	37.9/37.8
3-6-02	8:30	37.8/37.9
3-13-02	2:00	37.7/37.7
3-20-02	10:30	37.6/37.8
3-27-02	8:40	37.3/37.4
4-3-02	8:15	37.1/37.2
4-10-02	2:15	37.7/37.6

March 11

The Devices were Removed from the water bath and visually inspected without removing them from the glass vials. All devices were intact with all components and solder in their original position. The vials were placed back into the water bath.

QC Control
PW

Continued on Page 95

Read and Understood By

	4-12-02	Elsa Aldridge	6-25-2002
Signed	Date	Signed	Date

PROJECT Corrosion Test Vial Numbers + Test Dates. Notebook No. 239
Continued From Page: 68

April 10:

Group A: Vials numbered A-7-a, A-7-b, A-7-c were removed from the water bath. The devices were removed from the vials and ultrasonically cleaned in DI water for 2 minutes.

Group B: Vials numbered B-7 a thru B-7-F were removed from the water bath. The devices were removed from the vials and ultrasonically cleaned in DI water for 2 minutes.

RAG 6/25/02

Doc Control PW

Continued on Page 96

Read and Understood By

Signed 4-12-02 Date

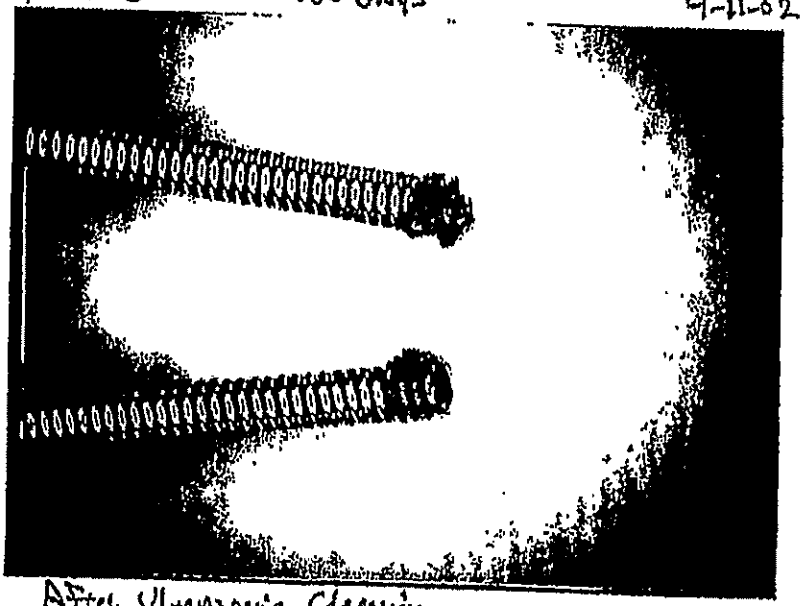
Elisa Aldridge Signed 6-25-2002 Date

PROJECT Corrosion Test Vial Numbers + Test Dates **Notebook No.** 239

Continued From Page 95

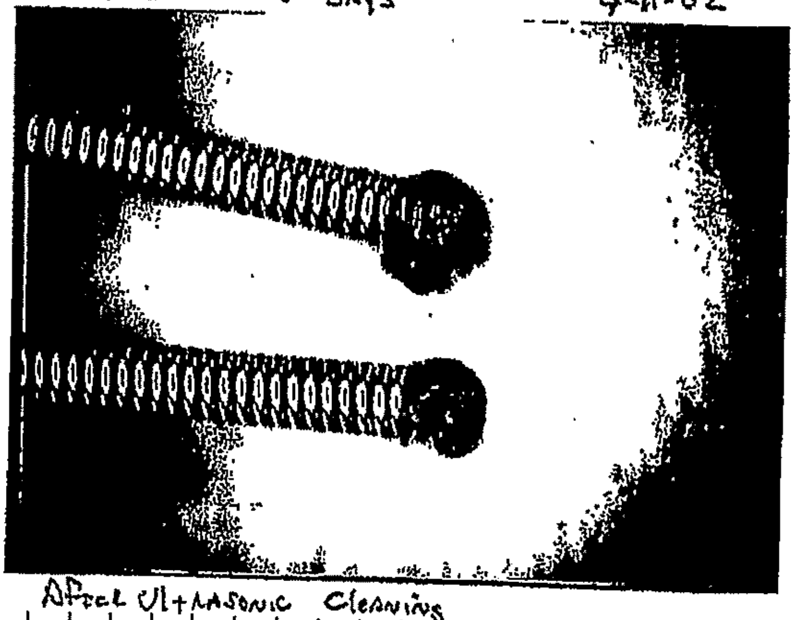
After Ultrasonic Cleaning EA 6-25-2002

B-7-B 180 days 4-11-02



After Ultrasonic Cleaning

B-7-C 180 DAYS 4-11-02



After Ultrasonic Cleaning

RA 6/25/02

RA 6/26/02

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VR 0191

Continued on Page 97

Read and Understood By

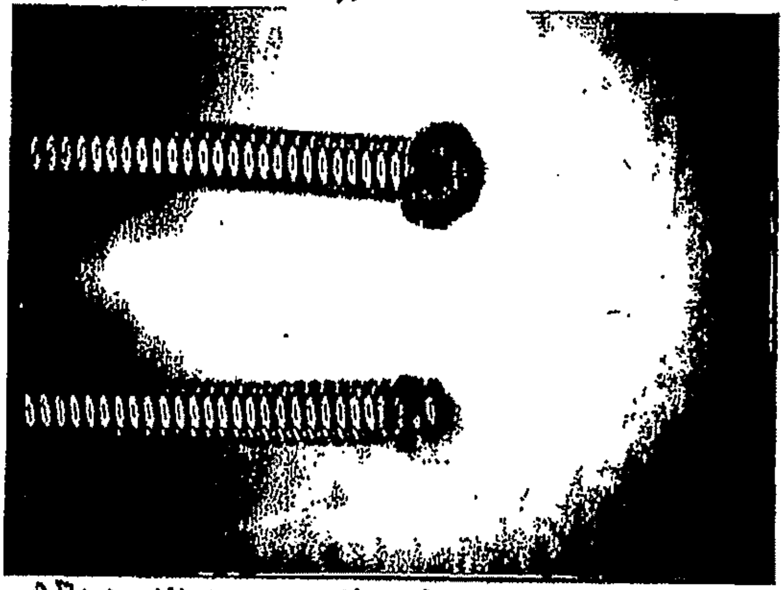
Cheryl — Signed 4-12-02 Date

Elisa Aldridge Signed 6-25-2002 Date

PROJECT Corrosion Test Vial Numbers + Test Dates **Notebook No.** 239

Continued From Page 96

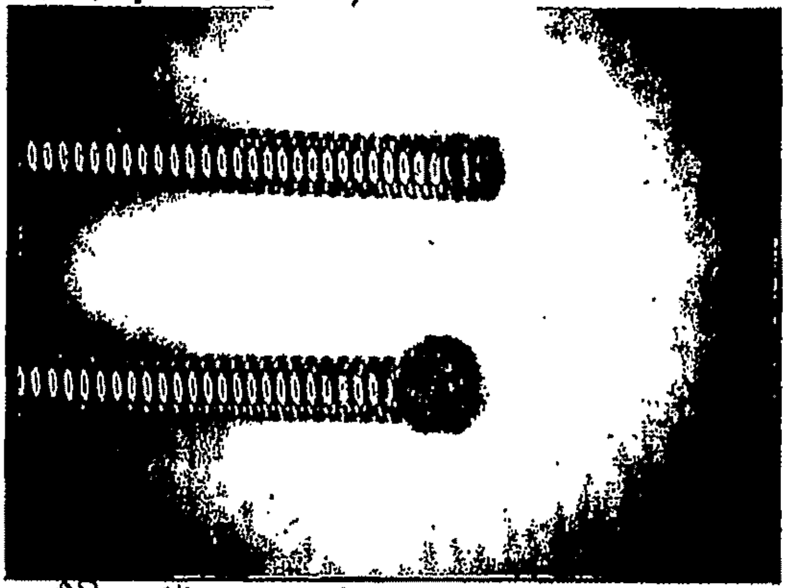
B-7-D 180 DAYS 4-11-02



After Ultrasonic Cleaning

RAS 6/25/02

B-7-F 180 DAYS 4-11-02



After Ultrasonic Cleaning

RAS 6/25/02

Doc Control PW

Continued on Page

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Cheryl — Signed — 4-12-02 Date

Elsa Alde — Signed — 6-25-2002 Date

PROJECT Corrosion test preparation (VR0191 pv rev 1) **Notebook No.** 248

Continued From Page —

Objective:

To document the preparation of solutions, samples and water bath for VR0191 pv rev 1. All documented steps were performed on 10/12/01.

Tools, equipment:

Beaker, capacity 250 ml, graduated, line at 150 ml ± 5%
Stainless steel tweezers
Temperature Gage Part # FA90694 cal: 3/22/01 Due 3/22/02
Water bath, thermostatically controlled
Disposable Pipettes, VWR part # 14670-330, cap. 5 ml
PH paper:

colorpHast	pH 2-9	Cat. 9578	~~Lot~~ Manuf. Lot#	00458060
colorpHast	pH 6.5-10.0	Cat 9583	Manuf. Lot #	00451990
colorpHast	pH 4.0-7.0	Cat 9582	Manuf. Lot #	OC107192
colorpHast	pH 0-14.0	Cat 9590	Manuf. Lot #	OC178457
ColorpHast	pH 7.5-14.0	Cat 9587	Manuf. Lot #	OC082141

Vials

Materials:

Sodium Chloride 0.85 - 0.90% Solution w/v Lot # RD 0128405
Part # E1880 exp. 5-31-02

Buffer Solution pH 7.0 Lot # RD 0128401 exp: 3-31-03
Part # E1879-04

Device Subassembly Lot # RD0129001 So # 1058
Part # E0648-02 rev C.

Doc Control
PW

VR 0191

Continued on Page 68

Read and Understood By

Signed 11/5/01 Date

Signed 1/10/02 Date

PROJECT Corrosion test preparation VP0191, pr rev 1

Notebook No. 248

Continued From Page 67

Solution preparation :

- Pour into 250 ml Beaker 150 ml of Sodium Chloride solution E1880
- Add 30 drops of pH 7.0 Buffer solution E1879-04
- Verify that pH is in the 6.0 - 7.0 range.

Sample preparation on 10/12/01

Location : Conceptus R/D Lab
Present : Jay Yang, Christian Lowe, Cheryl Swanson

A) Solution was prepared per the above formula pH was 6.5 ± 1/4 pH units as measured with pH papers listed under materials

B) Vials are labeled per VP0191, pr rev 1 Step 6

C) Vials from A series and B-1-a through B-1-f are filled with solution from a) and 2 devices were addeded to each vial, cap was sealed.

d) Three control vials labeled control I C-d were filled with
Control 2 C-e
Control 3 C-f
Solution and sealed With cap.

e) Three vials were labeled C-A Two devices were added to each vial and cap was sealed
C-B
C-C

f) Vials labeled B-2-a through B-2-f were filled with solution and Cap was sealed, in preparation for day 7, Step 16 of VP-0191, pr rev 1.

PS: Vials were filled to following level 

Right below thread

VR 0191

Continued on Page 69

Read and Understood By

Signed 11/5/01 Date

Signed 1/10/02 Date

PROJECT Corrosion test preparation VP0191.pv rev1

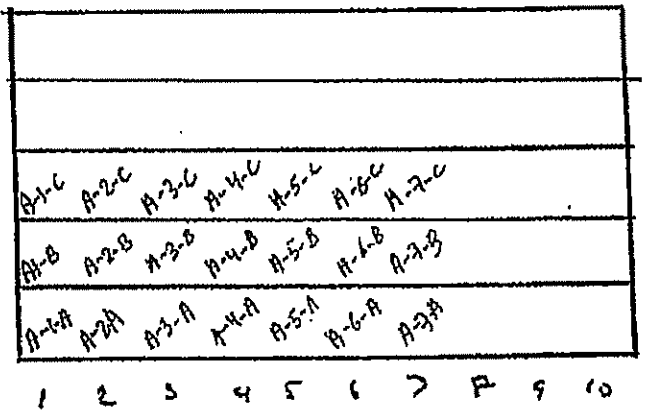
Continued From Page 68

Vial disposition in racks:

Two racks A) A series from VP0191.pv rev1
B) B series from VP0191.pv rev1

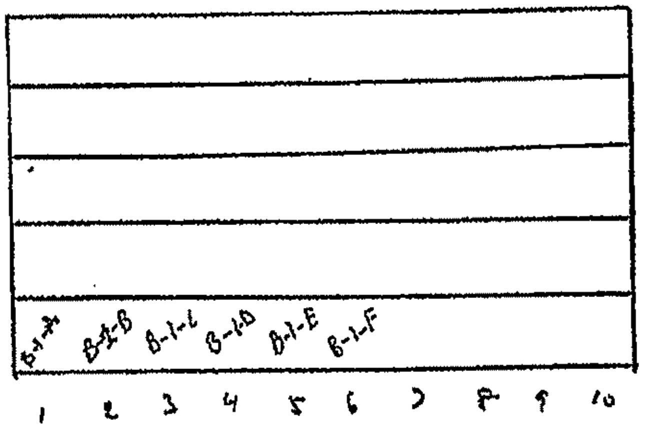
Schematic of disposition:

Rack A



11/5/11

Rack B



11/5/11

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PW

VR 0191

Continued on Page 70

Read and Understood By

	11/5/11		1/10/12
Signed	Date	Signed	Date

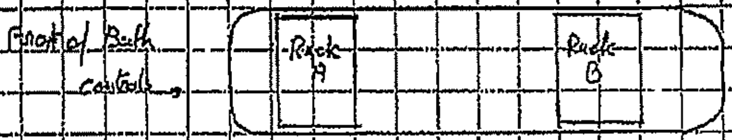
PROJECT Corrosion test preparation VP0191.pv rev1

Notebook No. 248

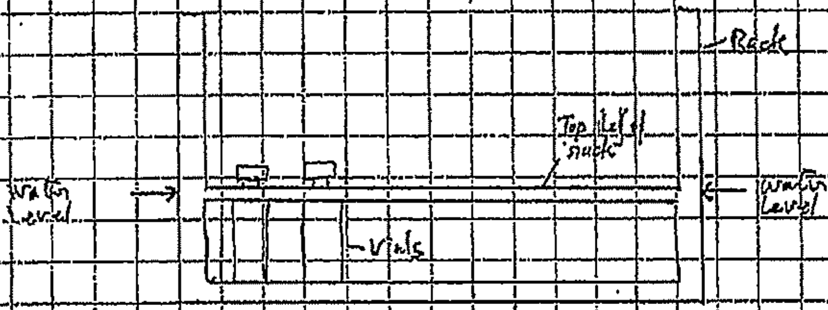
Continued From Page 63

Water Bath :-

Rack disposition in bath (Top view)



Water Level in bath - side view of rack



Racks were placed in water bath on 10/12/01 at 12'30 pm.

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PW

VR 0191

Continued on Page N/A

AKG/25/02

Read and Understood By

	11/5/01		1/2/02
Signed	**Date**	**Signed**	**Date**

PROJECT Corrosion test sample handling VP0191.pv rev1

Notebook No. 248

Continued From Page —

Objective: to describe sample manipulation steps during VP0191.pv rev 1

Group A:

1. Remove vials from rack
2. Using tweezers previously cleaned with alcohol, remove devices from vial
3. Clean devices by immerging in di water in ultrasonic cleaner for ~~1 min~~ 2 min cc 11/9/01 Air dry devices. Put into clean vials labeled with same code as the vial they came from
4. Keep all original solutions in the original vials, screw cap as tight.

Group B:

1. remove vials from rack
2. Using previously cleaned tweezer, remove devices from vial and place into appropriate destination vial (per VP0191.pv rev1) Wear gloves during manipulation, blot gently dry before putting device into destination vials. Close destination vial, tighten cap, replace in rack.
3. Keep solutions ~~into~~ cc 11/9/01 in original vials, tighten down cap. Store in cool place.

Doc Control PVN

VR 0191

Continued on Page —

Read and Understood By

Signed	Date	Signed	Date
	11/9/01		1/10/02

PROJECT Delivery of Solutions to analysis : VP0191. Vp rev1 **Notebook No.** 248

Continued From Page —

Scope : to record the delivery of solutions to analysis laboratory

Location / lab information : Scientific Environmental Labs
Palo Alto, CA

Samples delivered to J. Yang on 11/14/01 for hand delivery to lab

Cumulative :	A-1-A	7 day	Solution Controls :	
	A-1-B	7 day		
	A-1-C	7 day	C-d	control 1
	A-2-A	14 day	C-e	Control 2
	A-2-B	14 day	C-f	Control 3
	A-2-C	14 day		
	A-3-A	30 day		
	A-3-B	30 day		
	A-3-C	30 day		

With change of solution :

B-1-A	B-2-A	B-3-A
B-1-B	B-2-B	B-3-B
B-1-C	B-2-C	B-3-C
B-1-d	B-2-d	B-3-d
B-1-e	B-2-e	B-3-e
B-1-f	B-2-f	B-3-f

Doc Control
P.W.

VR 0191

Continued on Page /

Read and Understood By

Signed 11/14/01 Date

Signed 1/10/02 Date

PROJECT SEM Examination of corr. samples VP0191.vp rev 1 · Continued From Page —

Scope Per VP0191.pv rev 1., samples from corrosion test will be examined for evidence of corrosion by SEM examination.

Laboratory: Charles Evans Assoc., Wed 11/14/01, present: C-, Jay Yang

Samples

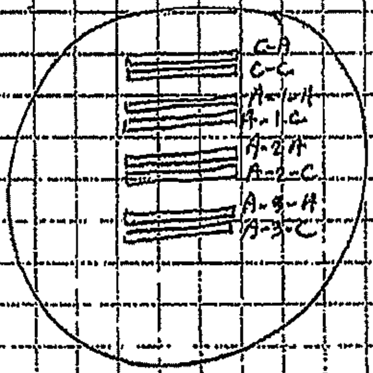
Controls	C-A	Cumulative	A-1-A	7 day
(0 day)	C-B		A-1-B	7 day
	C-C		A-1-C	7 day
			A-2-A	14 day
			A-2-B	14 day
			A-2-C	14 day
			A-3-A	30 day
			A-3-B	30 day
			A-3-C	30 day

SEM Model: Jeol JSM 5800LV

Operator: Han Wei Chen

Special sample prep: N/A

Layout



Doc Control
DAT

VR 0791

Continued on Page 74

Read and Understood By

Signed 11/14/01 Date

Signed 1/10/02 Date

74

PROJECT SEM Exam of corrosion samples VP0191. rev1 Notebook No. 248.

Continued From Page 73.

files	CA01 -	Ball tip	150x
	CA02 -	Ball tip	1000x
	CA 03 -	Inner coil	150x } 5th coil from I/O Bond
	CA 04 -	Inner coil	1000x }
	CA05 -	I/O Bond (distal end)	150x
	CA 06 -	I/O Bond	1000x
	CA07 -	Outer coil	150x
	CA08 -	Outer Coil	1000x
	CA09 -	Outer coil/Bond	150x
	CA10 -	outer coil/Bond	1000x
	CA11 -	Inner coil/Stopper	150x
	CA12	Inner coil/Stopper Solder	1000x
	CC01	I/O Bond at Niti coil	150x
	CC02	" " "	1000x
	A-3-C01	Ball tip	150x
	A3C02	Ball tip	1000x
	A3C03	Inner coil 5 coils distal I/O bond	150x
	A3C04	" " " " "	1000x
	A3C05	Inner I/O bond (distal)	150x
	A3C06	" " "	1000x
	A3C07	I/O bond at Niti	1000x
	A3C08	Outer Coil ribbon middle	150x
	A3C09	" " "	1000x
	A3C10	Outer/Bond	150x
	A3C11	" "	1000x
	A3C12	inner coil/Stopper	150x
	A3C13	" " "	1000x
	A3A01	I/O Bond /Niti	150x
	A3A02	" "	1000x
	A3A03	Outer to Band	1000x
	~~A3A04~~		

CL 11/14/01

<u>Note</u>: "CC" or "A3C" represents the sample name, and "01", "02" etc represent the picture number
CL 12/14/01

Doc Control

VR 0191

Continued on Page ~~~~ Page 76
CL 12/14/01

Read and Understood By

Signed 11/14/01 Date

Signed 1/10/02 Date

PROJECT SEM. examination of corrosion VP0191.VP

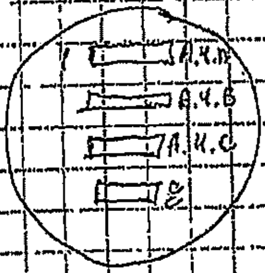
Notebook No.

Continued From Page 74

On 12/11/01, samples: A.4.A delivered by Clowe to Charles Evans Assoc.
A.4.B
A.4.C

Operator: Ali   Present: C. Lowe, J. Yang.
SEM Model: Jeol JSM 5800 LV

Layout on stage in SEM



below: "A4B" represents the sample name
"01" the photo number

A4B01	Ball tip	95X	
A4B02		1000X	
A4B03	Wire	100X	
A4B04		1000X	
A4.B05	Solder dist.	100X	
A4B06		1000X	
A4B07	Solder prox	150X	
A4B08	"	1000X	
A4B09	Solder flaking off on stopper band		150X
A4.B10	Stopper band @ solder/inner coil		150X
A4B~~11~~~~12~~11			1000X
A4B12	Outer coil		150X
A4B13	"		1000X
A4B14	Outer coil / Band		150X
A4B15	" "		1000X

Continued on Page 77

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PROJECT SEM Examination VR0191 pv rvd.

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al 12/14/02
~~A4B0~~

A4C01	Ball tip	35X
A4C02	"	1000X
A4C03	wire	150X
A4C04	"	1000X
A4C05	distal end of 1/o solder	150X
A4C06	" "	1000X
A4C07	inner coil stopper / solder	150X
A4C08	" " " "	1000X
A4C09	Outer coil	150X
A4C10	Outer coil	1000X
A4C11	outer coil / Band	150
A4C12	" "	1000X
A		
A4A01	1/o bond at wire ribbon	150X
A4A02		1000X

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VR 0191

Continued on Page

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Signed 1109/02 Date

Signed 1/11/02 Date

N/A

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PF

CORROSION STUDY 90 DAY SEM PHOTOS

SEM TECHNICIAN: JANE WHEELER
CHARLES EVANS & ASSOCIATES

ACCOMPANIED BY CONSULTANT, JAY XANG
PHOTOS TAKEN WED. 1-23-02.
PHOTOS ARE NOT INCLUDED IN THIS NOTEBOOK.

SAMPLE	PHOTO LABEL	DESCRIPTION
A-5-a	E5417 A-5-a-1	Ball tip, 100x
	E5417 A-5-a-2	Ball tip, 2000x
	E5417 A-5-a-3	Inner coil 4-5 coils distal to solder bond, 100x
	E5417 A-5-a-4	Inner coil, 2000x
	E5417 A-5-a-5	Solder bond close to proximal end, 100x
	E5417 A-5-a-6	Solder bond " , 2000x
	E5417 A-5-a-7	Nitinol ribbon very close to solder, 2000x
	E5417 A-5-a-8	Nitinol ribbon in middle of O.C., 100x
	E5417 A-5-a-9	Nitinol ribbon in middle of O.C., 2000x.
	E5417 A-5-a-10	Same as A-5-a-9, but darker
	E5417 A-5-a-11	Sandwich weld, 100x
	E5417 A-5-a-12	Sandwich weld, 2000x
	E5417 A-5-a-13	Solder at ¼ turn, 100x
	E5417 A-5-a-14	Solder at ¼ turn, 2000x
A-5-b	E5417 A-5-b-1	Ball tip, 100x
	E5417 A-5-b-2	Ball tip, 2000x
	E5417 A-5-b-3	Inner coil 4-5 coils distal to solder bond, 100
	E5417 A-5-b-4	Inner coil " , 2000x
	E5417 A-5-b-5	Solder bond, prox. end, 100x
	E5417 A-5-b-6	Solder bond, solder to inner coil transition, 200
	E5417 A-5-b-7*	Nitinol ribbon next to solder, 2000x
	E5417 A-5-b-9	Nitinol ribbon in middle of O.C., 100x.
	E5417 A-5-b-10	Nitinol ribbon in middle of O.C., 2000x
	E5417 A-5-b-11	Sandwich weld, 100x
	E5417 A-5-b-12	Sandwich weld, 2000x
	E5417 A-5-b-13	~~Sand~~ EA 1-24-02 Solder at ¼ turn, 100x.
	E5417 A-5-b-14	Solder at ¼ turn, transition to inner coil, 2000

* There was no photo labeled A-5-b-8.

VR 0191

Elisa Aldridge 02-19-02

Doc Control PW 2/21/02
Date

PROJECT CORROSION STUDY 90 DAY SEM PHOTOS

Continued From Page 70

SAMPLE	PHOTO LABEL	DESCRIPTION
A-5-c	E5417 A-5-c-1	Ball tip, 100x
	E5417 A-5-c-2	Ball tip, 2000x
	E5417 A-5-c-3	Inner coils, 4-5 coils distal to solder bond, 100x
	E5417 A-5-c-4	Inner coil, " , 2000x
	E5417 A-5-c-5	Solder bond, 100x
	E5417 A-5-c-6	Solder bond close to Nitinol ribbon, 2000x
	E5417 A-5-c-7	Nitinol ribbon close to solder bond, 2000x
	E5417 A-5-c-8	Nitinol ribbon in middle of O.C., 100x
	E5417 A-5-c-9	Nitinol ribbon in middle of O.C., 2000x
	E5417 A-5-c-10	~~Solder to~~ EA 1-24-02 Sandwich weld, 100x
	E5417 A-5-c-11	Sandwich weld, 2000x
	E5417 A-5-c-12	Solder at 1/4 turn, 100x
	E5417 A-5-c-13	Solder at 1/4 turn, transition from solder to inner coil, 2000x

Continued on Page N/A

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Signed 02-19-02 Date

Signed 2/21/~~01~~ 02 DT 2/21/02 Date

PROJECT CORROSION STUDY 180 DAY SEM IMAGES

Notebook No. 271

Continued From Page N/A

SEM SCIENTIST : JANE WHEELER
CHARLES EVANS & ASSOCIATES
APRIL 15, 2002

EA 5-23-02

EACH VIAL CONTAINED 2 SAMPLES. ONLY 1 SAMPLE FROM EACH VIAL WAS IMAGED. GROSS EXAMINATION OF THE DEVICES SHOWED NO DIFFERENCE BETWEEN THE IMAGED DEVICES AND THE DEVICES THAT WERE NOT IMAGED. THE DEVICES WERE RANDOMLY SELECTED FOR IMAGING

PURPOSE : GET SEM IMAGES OF 180-DAY CORROSION SAMPLES
TODAY: IMAGE A-7-A, A-7-B, A-7-C, C-C
ON LATER DATES, IMAGE C-A, C-B, B-7-A thru B-7-E

PROCEDURE : TOOK FULL ~~PHOTOS~~ IMAGES EA 4-15-2002 (14-15 IMAGES) OF SAMPLE A-7-A. TOOK IMAGES ONLY OF THE SOLDER FOR THE REMAINING SAMPES.

DATA : IMAGES SAVED ON CD MARKED E5615. HARD COPIES WERE ALSO PRINTED.

THE SEM TOOK A LONG TIME (APX 20 MIN.) TO PULL A VACUUM BECAUSE THE SAMPLES WERE NOT COMPLETELY DRY. J. WHEELER RECOMMENDED PLACING ANY FUTURE SAMPLES UNDER A HEAT LAMP FOR 15-20 MINUTES TO DRY THEM MORE COMPLETELY.

APRIL 22, 2002

PURPOSE & PROCEDURE : SAME AS ABOVE EXCEPT TODAY IMAGE C-A, C-B, B-7-E, B-7-F. DO FULL SET OF IMAGES ON C-A. ALL OTHERS, JUST IMAGE SOLDER.

SAMPLE B-7-E OUTER COIL GOT STRETCHED OUT WHEN MOUNTING

DATA : IMAGES SAVED ON CD MARKED E5616 04/22/2002
HARD COPIES ALSO MADE.

Continued on Page 85

Elisa Aldridge	5-22-2002	Read and Understood By	Doc Control PW 5/23/02
Signed	Date	Signed	Date

PROJECT CORROSION STUDY 180 DAY SEM IMAGES Notebook No. 271
Continued From Page 74

SEM SCIENTIST: JANE WHEELER
CHARLES EVANS & ASSOCIATES
APRIL ~~25~~, 2022 1:00-3:00pm
30 EA 5-23-2002

PURPOSE: IMAGE SAMPES B-7-A, B-7-B, B-7C, B-7-D
DO FULL SET OF IMAGES FOR SAMPLE B-7-C. FOR THE OTHERS, JUST IMAGE SOLDER AND ANY UNUSUAL FEATURES IE ANYTHING DIFFERENT FROM B-7-C.

DATA:

SAMPLE	FILE NAME	DESCRIPTION	MAGNIFICATION
B-7-A	a1-E5631	BALL TIP	110 X
	a2-E5631	BALL TIP	2000 X
	a3-E5631	IC/OC SOLDER BOND	100 X
	a4-E5631	IC/OC SOLDER BOND	2000 X
	a5-E5631	STOPPER SOLDER	100 X
	a6-E5631	STOPPER SOLDER	2000 X
B-7-B	b1-E5631	BALL TIP	LOW
	b2-E5631	BALL TIP	HIGH
	b3-E5631	IC/OC SOLDER BOND	LOW
	b4-e5631	IC/OC SOLDER BOND	HIGH
	b5-e5631	STOPPER SOLDER	LOW
	b6-e5631	STOPPER SOLDER	HIGH
B-7-C	c-e5631	BALL TIP (GONE)	LOW
	c2-e5631	BALL TIP SOLDER	HIGH
	c3-e5631	IC DISTAL ~~PROX.~~ TO SOLDER BOND	LOW
	c4-e5631	IC DISTAL ~~PROX.~~ TO SOLDER BOND	HIGH
	c5-e5631	IC/OC SOLDER BOND, DISTAL ~~PROXIMAL~~ END	LOW
	c6-e5631	IC/OC SOLDER BOND, PROX, ~~DIS DISTA~~ END	LOW

4 distal/prox. redlines/corrections EA 5-22-2002

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Signed 5-22-2002 Date

Read and Understood By

Signed Doc Control PW 5/23/02 Date

PROJECT CORROSION STUDY 180 DAY SEM IMAGES

Notebook No. 271

Continued From Page 85

DATA CONTINUED:	SAMPLE	FILE NAME	DESCRIPTION	MAGNIFICATION
	B-7-C	c7-e5631	IC/OC SOLDER BOND, PROX.	HIGH
		c8-e5631	NITINOL OC CLOSE TO SOLDER BOND	HIGH
		c9-e5631	OC, MIDDLE COIL	LOW
		c10-e5631	OC, MIDDLE COIL	HIGH
		c11-e5631	STOPPER SOLDER (OC ALSO IN IMAGE)	LOW
		c12-e5631	STOPPER SOLDER	HIGH
		c13-e5631	SANDWICH WELD	LOW
		c14-e5631	SANDWICH WELD	HIGH
		c15-e5631	SANDWICH WELD	HIGH
	B-7-D	d1-e5631	BALL TIP	LOW
		d2-e5631	BALL TIP	HIGH
		d3-e5631	IC/OC SOLDER BOND	HIGH
		d4-e5631	IC/OC SOLDER BOND DISTAL END	LOW
		d5-e5631	STOPPER SOLDER	LOW
		d6-e5631	STOPPER SOLDER	HIGH
		d7-e5631	SANDWICH WELD	LOW
		d8-e5631	SANDWICH WELD	HIGH

OBSERVATIONS: ON SAMPLE B-7-D, THERE WAS A SPOT NEAR THE SANDWICH WELD THAT APPEARED AS A DIFFERENT COLOR WHEN IMAGED. JANIE WHEELER SAID IT LOOKED LIKE SALT RESIDUE AND NOT CORROSION.

ALL THE SOLDER SHOWED SIGNS OF CORROSION. THE BALL TIPS CORRODED DRAMATICALLY, THE STOPPER SOLDER SHOWED A LOWER LEVEL OF CORROSION, AND THE IC/OC SOLDER BOND SHOWED THE LEAST CORROSION DAMAGE. NO SAMPLES FELL APART OR HAD IC/OC SEPARATION.

87 EA 5-23-02

Continued on Page N/A

VR 0191

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Doc Control PW

Signed	Date	Signed	Date
	5-22-2002		5/23/02

THE CORROSION SAMPLES ARE FROM CORROSION STUDY:
VR-0191. PV. REV

THE FULL EXPLANATION OF THE CORROSION STUDY DESCRIBES WHAT EACH SAMPLE IS, BUT A BRIEF DESCRIPTION IS:

IF THE SAMPLE STARTS W/ THE LETTER "A", THE SALINE IN THE VIAL WAS NOT CHANGED SEVERAL TIMES OVER THE 6 MONTHS.

IF THE SAMPLE STARTS WITH "B", THE SALINE WAS CHANGED

IF THE SAMPLE STARTS WITH "C", IT IS A CONTROL SAMPLE THAT WAS STORED IN AIR AT ROOM TEMP.

N/A

Continued on Page

Read and Understood By

Elsa Aldinof 5-23-2002
Signed Date

5/23/02
Signed Date

Doc Control
PW

APPENDIX 5

SEL
SCIENTIFIC ENVIRONMENTAL
LABORATORIES, INC.

Conceptus, Inc.
1021 Howard Ave.
San Carlos, CA 94070

Mr. Jay Young

Released: 11-27-01
Lab ID : 016836-016865
Recv'd : 11-16-01
Sampler : Conceptus
Analyst : DH
Matrix : Liquid

Source	Results (mg/L)		
	Nickel	Chromium	Tin
A-1 A	0,05	< 0.05	7.9
A-1 B	0.22	< 0,05	41
A-1 C	0.10	< 0.05	12
A-2 A	0,23	< 0,05	38
A-2 B	0,16	< 0,05	59
A-2 C	0,22	< 0,05	50
A-3 A	0,05	< 0,05	2,8
A-3 B	0,35	< 0,05	67
A-3 C	0.12	< 0.05	19
B-1 A	0.17	< 0,05	25
B-1 B	0,24	< 0,05	35
B-1 C	0,23	< 0,05	39
B-1 D	0.22	< 0,05	48
B-1 E	0,18	< 0.05	27
B-1 F	0.31	< 0,05	13
B-2 A	< 0,05	< 0,05	26
B-2 B	< 0,05	< 0,05	28
B-2 C	< 0,05	< 0,05	27
B-2 D	< 0,05	< 0,05	35
B-2 B	< 0,05	< 0,05	29
B-2 F	< 0,05	< 0,05	35
B-3 A	< 0,05	< 0,05	13
B-3 B	< 0,05	< 0,05	2,0
B-3 C	< 0,05	< 0,05	3,6
B-3 D	< 0,05	< 0,05	1.8
B-3 E	< 0,05	< 0,05	3,5
B-3 F	< 0,05	< 0,05	5,9
Control 1 C-D	< 0,05	< 0,05	< 0,05
Control 2 C-E	< 0,05	< 0,05	< 0,05
Control 3 C-F	< 0,05	< 0,05	< 0,05

Nickel – EPA # 249,2 Detection Limit 0,05 mg/L
Chromium – EPA # 218,2 Detection Limit 0.05 mg/L
Tin – EPA # 282,2 Detection Limit 0,05 mg/L

SP:dc

Shui Fong
Director, Water Laboratory

Doc Control
PW

State Certified Water Laboratory for Chemical and Biological Examination
924 Industrial Avenue Palo Alto, CA 94303 650 856-6011 FAX 650 856-4281

SEI

SCIENTIFIC ENVIRONMENTAL
LABORATORIES, INC.

Conceptus, Inc.
1021 Howard Ave.
San Carlos, CA 94070

Mr. Jay Young

Released: 12-14-01
Lab ID : 017352-017360
Recv'd : 12-11-01
Sampler : Conceptus
Analyst : DH
Matrix : Liquid

Source	Results (mg/L)		
	Nickel	Chromium	Tin
A-4 A	0.07	<0.05	16.3
A-4 B	<0.05	<0.05	10.8
A-4 C	<0.05	<0.05	4.2
B-4 A	<0.05	<0.05	3.0
B-4 B	<0.05	<0.05	1.2
B-4 C	<0.05	<0.05	1.7
B-4 D	<0.05	<0.05	3.2
B-4 E	<0.05	<0.05	4.8
B-4 F	<0.05	<0.05	2.7

Nickel – EPA # 249.2 Detection Limit 0.05 mg/L
Chromium – EPA # 218.2 Detection Limit 0.05 mg/L
Tin – EPA # 282.2 Detection Limit 0.05 mg/L

Shui Fong
Director, Water Laboratory

SF:dc

VR 0191

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SEL

SCIENTIFIC ENVIRONMENTAL
LABORATORIES, INC.

Conceptus, Inc.
1021 Howard Ave.
San Carlos, CA 94070

Mr. Jay Yang

Released: 1-24-02
Lab ID : 020332-020340
Recv'd : 1-18-02
Sampler : Conceptus
Analyst : DH
Matrix : Liquid

Source	Results (mg/L)		
	Nickel	Chromium	Tin
A-5 A	< 0.05	< 0.05	2.2
A-5 B	< 0.05	< 0.05	4.5
A-5 C	< 0.05	< 0.05	4.4
B-5 A	< 0.05	< 0.05	5.1
B-5 B	< 0.05	< 0.05	1.4
B-5 C	< 0.05	< 0.05	0.5
B-5 D	< 0.05	< 0.05	0.7
B-5 E	< 0.05	< 0.05	0.9
B-5 F	< 0.05	< 0.05	2.0

Nickel – EPA # 249.2 Detection Limit 0.05 mg/L
Chromium – EPA # 218.2 Detection Limit 0.05 mg/L
Tin – EPA # 282.2 Detection Limit 0.05 mg/L

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LABORATORIES, INC.

Conceptus, Inc.
1021 Howard Ave.
San Carlos, CA 94070

Ms. Elisa Aldridge

Released: 2-28-02
Lab ID : 020941-020949
Recv'd : 2-22-02
Sampler : Conceptus
Analyst : DH
Matrix : Liquid

Source	Results (mg/L)		
	Nickel	Chromium	Tin
A-6 A	0.10	< 0.05	17.6
A-6 B	0.05	< 0.05	7.0
A-6 C	0.05	< 0.05	6.3
B-6 A	< 0.05	< 0.05	0.69
B-6 B	< 0.05	< 0.05	0.33
B-6 C	< 0.05	< 0.05	< 0.05
B-6 D	< 0.05	< 0.05	0.15
B-6 E	< 0.05	< 0.05	0.61
B-6 F	< 0.05	< 0.05	17.6

Nickel – EPA # 249.2 Detection Limit 0.05 mg/L
Chromium – EPA # 218.2 Detection Limit 0.05 mg/L
Tin – EPA # 282.2 Detection Limit 0.05 mg/L

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924 Industrial Avenue Palo Alto, CA 94303 650 856-6011 FAX 650 856-4281

SCIENTIFIC ENVIRONMENTAL
LABORATORIES, INC.

Conceptus, Inc.
1021 Howard Ave.
San Carlos, CA 94070

Ms. Elisa Aldridge

Released: 4-23-02
Lab ID : 021777-021785
Recv'd : 4-11-02
Sampler : Conceptus
Analyst : DH
Matrix : Liquid
Revised

Source	Results (mg/L) Nickel	Chromium	Tin
A-7 A	0.04	< 0.05	5.2
A-7 B	0.14	< 0.05	5.9
A-7 C	0.40	< 0.05	11.6
B-7 A	0.03	< 0.05	0.09
B-7 B	0.05	< 0.05	0.05
B-7 C	0.02	< 0.05	0.07
B-7 D	0.05	< 0.05	0.05
B-7 E	0.05	< 0.05	0.14
B-7 F	0.03	< 0.05	0.60

Nickel – EPA # 249.2 Detection Limit 0.02 mg/L
Chromium – EPA # 218.2 Detection Limit 0.05 mg/L
Tin – EPA # 282.2 Detection Limit 0.05 mg/L

Shui Fong
Director, Water Laboratory

SF:dc

VR 0191

Attachment 1

Corrosion Susceptibility Test Protocol on Conceptus Essure™ pbc device	V P0191.pv rev1	
	10/11/01	

Corrosion Susceptibility Test Protocol
Conceptus Essure^{TM} pbc device

Approvals:

Document Originator	Jay Yang, PhD Consultant Global Nitinol Technologies	Date: 10. 12. 01
Research and Development		Date: 10.12.01
Regulatory Affairs		Date: 10/12/2001

Doc Control PW

VR 0191

Corrosion Susceptibility Test Protocol on Conceptus Essure^{TM} pbc device	V P0191.pv rev1	
	10/11/01	

Objective

To evaluate the corrosion susceptibility of the implantable Essure^{tm} pbc device.

Background

Corrosion and its effects on structural integrity and biocompatibility are important part of design validation on efficacy and safety of implantable medical devices, especially when the device is made of dissimilar metals. Since an implanted Essure^{tm} pbc device is made of several types of materials (Tin solder, nitinol, 316L stainless steel, platinum), it is recommended to conduct a corrosion test to assess potential risks associated with galvanic corrosion.

Scope

1. To determine maximum leaching rate of toxic metal ions (Ni, Sn, Cr, specifically) in a simulated body environment.
2. To determine minimum time needed for structural disintegration /detachment in a simulated body environment.

Highlights of Methods

1. Samples: n=60 actual devices (implantable portion only) with current validated processes.
2. Simulated environment: immersion in a 0.9% NaCl physiological saline solution at 37 +/-1°C for up to 6 months. The pH value of the saline will be buffered between 6.0 and 7.0 at the beginning of the test. Corrosion data will be collected both in a cumulative sampling method (individual sample groups will be used for selected time points and solutions will not be changed during the sampling periods) and in a disruptive sampling method (same sample groups will be used for all selected time points and only solutions will be changed at the selected time points).
3. Analytic methods: (a) Using atomic absorption spectroscopy to measure leaching rate of metal ions (Ni, Sn, Cr) periodically for up to 6 months; and (b) use scanning electron microscopy (SEM) to record surface condition and components integrity periodically for up to 6 months.

Reference Documents

1. ASTM F746-87: "Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials"
2. "Medical and Biological Effects of Environmental Pollutants - Nickel", published by the National Academy of Sciences, Washington, D.C., 1975.
3. Measurement of trace element Nickel by atomic absorption spectroscopy, test method EPA 249.2

4. Measurement of trace element Chromium by atomic absorption spectroscopy, test method EPA 218.2
5. Measurement of trace element Tin by atomic absorption spectroscopy, test method EPA 282.2

Materials and Equipment

Implantable devices, p/n E0648-02 , Qty 60
Water bath with temperature control at +/-1°C.
Distilled water
Optional Polypropylene balls, hollow
Physiological saline solution, 0.9% NaCl
Buffer solutions pH 6.0, pH 7.0, pH 8.0, pH 5.0
Glass vials, 4 ml, with Teflon sealed screw top
Vial rack or glass containers with screw top
Pipette and suction bulb
Electronic temperature gage (calibrated, see report for calibration information) .

Procedure

1. Fill the water bath with distilled water.
2. Add polypropylene balls to top surface of water in the bath so that the entire top surface is covered (this will reduce evaporation of water from the bath).
3. Set water bath temperatures to 37° Celsius.
4. Allow baths to heat for 2 hours to allow temperatures to stabilize.
5. Confirm temperature of bath; recalibrate temperature control of bath if necessary using procedure detailed in instruction manual of bath. Check and note temperature of bath at minimum once a week. Check water level at least once a week, to make sure vials are between 50% and 80% immerged in the water of the bath.
6. Prepare thirty (30) glass vials and divide them into three groups (A, B, C) by marking each as follows with an indelible ink marker:

A-1-a:	7 days, cumulative
A-1-b:	7 days, cumulative
A-1-c:	7 days, cumulative
A-2-a:	14 days, cumulative
A-2-b:	14 days, cumulative
A-2-c:	14 days, cumulative
A-3-a:	30 days, cumulative
A-3-b:	30 days, cumulative
A-3-c:	30 days, cumulative
A-4-a:	60 days, cumulative
A-4-b:	60 days, cumulative
A-4-c:	60 days, cumulative
A-5-a:	90 days, cumulative
A-5-b:	90 days, cumulative

A-5-c:	90 days, cumulative
A-6-a:	120 days, cumulative
A-6-b:	120 days, cumulative
A-6-c:	120 days, cumulative
A-7-a:	180 days, cumulative
A-7-b:	180 days, cumulative
A-7-c:	180 days, cumulative

B-x-a:	x=1,2,3,4,5,6,7, representing 7, 14, 30, 60, 90, 120, 180 days
B-x-b:	x=1,2,3,4,5,6,7, representing 7, 14, 30, 60, 90, 120, 180 days
B-x-c:	x=1,2,3,4,5,6,7, representing 7, 14, 30, 60, 90, 120, 180 days
B-x-d:	x=1,2,3,4,5,6,7, representing 7, 14, 30, 60, 90, 120, 180 days
B-x-e:	x=1,2,3,4,5,6,7, representing 7, 14, 30, 60, 90, 120, 180 days
B-x-f:	x=1,2,3,4,5,6,7, representing 7, 14, 30, 60, 90, 120, 180 days

C-a:	Control / reference, device only
C-b:	Control / reference, device only
C-c:	Control / reference, device only
C-d:	Control / reference, solution only
C-e:	Control / reference, solution only
C-f:	Control / reference, solution only

7. Prepare Sixty (60) implantable devices using current engineering procedures, including the heat treatment, cleaning, and inspection criteria. Sterilization is not necessary. Record complete history of the devices.
8. Take scanning electron micrographs (SEM's) of six (6) devices as control or reference. Micrographs should be taken at both lower magnification and high magnification at representative locations: solder joint, weld joint, inner coil, and outer coil.
9. Place two (2) of the devices into each of the all vials, except for c-d, c-e, c-f.
10. Add minimum amount of the pH 6.0 buffer solution to set the saline solution at pH between 6.0 and 7.0.
11. Using the pipette and suction bulb, add sufficient physiological saline solution to the first vial to fully cover all devices. Note exact amount added. Close screw cap tightly.
12. Add this same volume of saline, measured with the pipette, to all other glass vials except for the C-a, C-b and C-c vials. Close all vial lids tightly. Send solution control samples C-d, C-e, C-f to a contract lab for trace elements (Ni, Sn, Cr) analysis.
13. Place the vials in water bath set to 37°C. The vials may need to be weighted down or fixed onto a rack to keep it submerged. Replace cover on water bath and note date and time.
14. Keep the three vials labeled "control" at room temperature in a cool place. Keep the lids tightly closed. No temperature control is required.
15. At 7 days after the start of the test, remove the vials labeled "7 days" in sample group A from the water bath. Remove all devices from each vial; ultrasonically clean the

devices and place them in new, labeled vials. Send the aged solution of each vial to a contract lab for trace elements (Ni, Sn, Cr) analysis and the devices of each vial for SEM analysis. SEM Micrographs should be taken both at lower magnification and higher magnification at each representative locations: solder joint, weld joint, inner coil, and outer coil, with focuses on specific corrosion signs such as pits, cracking, massive erosion, and detachment of joints.

16. Similarly, at 7 days after the start of the test, remove the vials labeled "7 days" in sample group B from the water bath. Remove all devices from each vial and place them in new, labeled vials. Fill the new vials with the same amount (4 ml) of fresh buffered saline solution and close the lids tightly. Place the new vials back into the water bath. Send the aged solutions to a contract lab for trace elements (Ni, Sn, Cr) analysis.
17. Repeat Steps 15 and 16 at 14 days.
18. Repeat Steps 15 and 16 at 30 days.
19. Repeat Steps 15 and 16 at 60 days. In addition, perform SEM analysis on devices from sample group B. Ultrasonically clean the devices before and after SEM handling.
20. Repeat Steps 15 and 16 at 90 days.
21. Repeat Steps 15 and 16 at 120 days.
22. Repeat Steps 15 and 16 at 180 days. In addition, perform SEM analysis on devices from sample group B. Ultrasonically clean the devices before and after SEM handling
23. Analyze data and write an intermediate report at about 2-months of data points and a final report of findings when the test ends.

Acceptance Criteria

1. The measured maximum corrosion rate must be such that the resulting amount of equivalent nickel release is less than the normal human intake of nickel from the natural environment, which is 0.3 to 0.6 mg per day, as published in reference 2.
2. There is no complete detachment of the components caused by corrosion within first 3 months of the tested time periods.

Results and Conclusions

All build documentation for the samples, calibration information and test data will be included in a final report.
The results and conclusions of all tests shall be documented in a final report.

Attachment 2

Addendum to
Corrosion Susceptibility Test Protocol
On Conceptus Essure Device

VP-0191.PV.Rev1 A01

Approvals:

Document Originator	Elisa Aldridge	Elisa Aldridge	Date: 2-22-02
Research and Development	Ashish Khera	Betsy ... for AK	Date: 2-22-02
Regulatory Affairs	Susan Aloyan		Date: 3-4-2005

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Summary

This addendum describes and approves a deviation from the original protocol, VP-0191.PV.Rev1. An uncalibrated water bath may be used for the validation. This is an acceptable deviation, because the water temperature is being monitored with a calibrated electronic temperature gage.

Original Protocol Requirements

1. Required equipment includes:
   - 1.1 Water bath with temperature control at +/-1°C
   - 1.2 Electronic temperature gage
   - 1.3 Unless specified otherwise in a validation protocol, only calibrated equipment may be used in a validation.
2. Step 5 of the procedure includes:
   - 2.1 Confirm the temperature of the bath is 37 ± 1° C before setting the samples in the water bath.
   - 2.2 Check and note temperature of bath at minimum once a week.

Deviation

VP-0191.PV.Rev1 may be performed using an uncalibrated water bath as long as a calibrated temperature gage is used to monitor the temperature of the water bath. The original protocol did not clearly state that an uncalibrated water bath is acceptable.

Justification

1. The temperature is being monitored at least once a week using a calibrated electronic temperature gage.
2. During the 4 months that the test has been running, the water bath temperature has varied from 36.1° C to 37.8° C. This is within the range required by the protocol. The data is located in lab notebook # 239, pages 64 and 65.