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Title: ELECTROCHEMICAL EVALUATION OF INSTENT

PROJECT ADMINISTRATION DATA

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INSTENT INC.
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Administrative comments -
INITIATION OF 3-MOS 'FIXED-PRICE' SPECIALIZED SERVICES AGREEMENT.

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GEORGIA INSTITUTE OF TECHNOLOGY
OFFICE OF CONTRACT ADMINISTRATION

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NOTICE OF PROJECT CLOSEOUT

S: 4/18/97

Closeout Notice Date 04/18/96

Project No. E-18-X60 | Center No. 10/24-6-R8816-0A0

Project Director MAREK M I | School/Lab MSE

Sponsor INSTENT INCORPORATED/EDEN PRAIRIE, MN

Contract/Grant No. AGMT DTD. 2/1/96 | Contract Entity GTRC

Prime Contract No.

Title ELECTROCHEMICAL EVALUATION OF INSTENT

Effective Completion Date 960401 (Performance) 960415 (Reports)

Closeout Actions Required:	Y/N	Date Submitted
Final Invoice or Copy of Final Invoice	Y	
Final Report of Inventions and/or Subcontracts	N	
Government Property Inventory & Related Certificate	N	
Classified Material Certificate	N	
Release and Assignment	N	
Other	N	

Comments

Subproject Under Main Project No.

Continues Project No.

Distribution Required:

Project Director	Y
Administrative Network Representative	Y
GTRI Accounting/Grants and Contracts	Y
Procurement/Supply Services	Y
Research Property Managment	Y
Research Security Services	N
Reports Coordinator (OCA)	Y
GTRC	Y
Project File	Y
Other	N
	N

E 18-X60
#1

Final Report

CORRESION EVALUATION OF *In*Stent CORONARY, VASCULAR AND CAROTID STENTS IN RINGER'S SOLUTION

By:
Miroslav Marek, Ph.D.
School of Materials Science and Engineering

Under:
Contract #: AGMT DTD. 2/1/96
InStent Inc.
6271 Bury Drive
Eden Prairie, MN 55346

Period of Performance:
01/01/96 - 04/01/96

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1. OBJECTIVE

The objective of the test program was to evaluate the corrosion behavior of *In*Stent coronary, vascular and carotid stents under conditions simulating the environment of the stents in the human body, using electrochemical test methods.

2. MATERIALS AND DEVICES

The following materials and devices were received from *In*Stent, Inc. for testing:

1. *In*Stent CardioCoil™ coronary stents (20 ea)
2. *In*Stent VascuCoil™ vascular stents (5ea)
3. InStent Carotid stents (6ea) (Lot Nos. 52, 54, 56, 57, 58, 59)

The emphasis in this corrosion test program was on the evaluation of the coronary stents. Limited tests have been performed for the vascular and carotid stents to determine if their behavior was substantially different from that of the coronary stents.

3. METHODOLOGY

The electrochemical tests of the corrosion behavior have included corrosion potential *vs.* time measurements, potentiodynamic anodic polarization and repassivation measurements, and long-term corrosion rate measurements. The tests were performed using Ringer's solution as a body fluid substitute, at 37°C and pH 7.4. For the corrosion potential and corrosion rate measurements the solution was saturated with a gas mixture containing 10% oxygen, 5% carbon dioxide, and balance nitrogen. For the polarization measurements the solution was deoxygenated (deaerated) using an anaerobic mixture of nitrogen with 5% carbon dioxide. Test protocols for all the tests are included in Appendix I. The test matrices for the coronary, vascular and carotid stents are shown in Tables 1, 2 and 3, respectively.

The main corrosion parameters were determined and the means were compared using t-test at $\alpha = 0.05$ and $\alpha = 0.01$.

4. TEST RESULTS

4.1 CardioCoil™ Coronary Stents

4.1.1 Potential *vs.* Time

In the medium-term tests the total exposure time was15-16 hours. The results are shown in Fig. 1 and Table 4. Generally, the corrosion potential showed some initial variation but was almost stable after about 6 hours. The mean potential at 15 hours of exposure was -0.128 V (SCE) (S.D. 0.040, n=6). Four coronary stents were also tested for long-term corrosion behavior, and the corrosion potential was monitored for 25 days. A plot of the corrosion potential *vs.* exposure time for these specimens is shown in Fig. 2. The corrosion potentials for the four specimens after 10 days of exposure ranged from -0.121 to -0.077 V (SCE); the mean potential for all four specimens during this time period was -0.099 V (SCE) (S.D. 0.016, n=4).

4.1.2 Potentiodynamic Anodic Polarization Curves

The nine polarization curves obtained at the standard scanning rate of 10 mV/min have been overlayed in Fig. 3. Critical test parameters are listed in Table 4. The polarization curves showed a passive region extending from the zero current potential (about -0.35 to -0.45 V, SCE) to a breakdown potential. The mean value of the breakdown potential was +0.180 V (SCE) (S.D. 0.125, n=9). At the faster scanning rate (60 mV/min) used in some of the repassivation tests the mean breakdown potential was +0.196 V (S.D. 0.114, n=5). Since there was no statistically significant difference between the two means at $\alpha = 0.05$ both sets of results for the breakdown potential were pooled. The mean breakdown potential of the pooled results was +0.186 V (SCE) (S.D. 0.117, n=14).

Following the breakdown there was a rapid increase in the corrosion current, indicating an onset of localized attack in the form of pitting.

4.1.3 Repassivation Test Results

Three cyclic tests were performed at the standard slow potential scanning rate (10 mVmin) and five at the faster scanning rate (60 mV/min). The results are shown in Figs 4 and 5 for the slow and faster scanning rate, respectively, and repassivation potentials are listed in Table 4. All test results showed a hysteresis confirming that the breakdown was due to a localized pitting attack and that a lower, repassivation potential had to be reached for repassivation. The mean value of the repassivation potential was -0.124 V (SCE) (S.D. 0.020, n=3) at the slower scanning rate, and -0.127 V (SCE) (S.D. 0.043, n=5) at the faster scanning rate. There was no statistically significant difference between the two means at $\alpha = 0.05$, and both sets of results were pooled. The mean breakdown potential of the pooled results was -0.126 V (SCE) (S.D. 0.035, n=8), and the range was from -0.185 to -0.064 V (SCE).

4.1.4 Potentiodynamic Current Density in the Passive State

The potentiodynamic current density in the passive state was determined at the mean open circuit corrosion potential, i.e., -0.128 V (SCE). For the coronary stents the current density was affected by the potential scanning rate; the mean value was 9.92E-9 A/cm^2 (S.D. 4.9E-9, n=9) for the slower scanning rate, and 5.30E-8 A/cm^2 (S.D. 4.21E-8, n=5) for the faster scanning rate. The difference was statistically significant at α=0.05, and the results were not pooled.

4.1.5 Long-term Corrosion Rate

The long-term corrosion current density was determined for four specimens by measuring periodically the Polarization Resistance R_p using the Linear Polarization Technique. The total exposure time was 26 days. The cathodic Tafel slope was measured in separate tests by recording potentiodynamic cathodic polarization curves for six specimens using the aerated Ringer's solution. The cathodic curves yielded the mean cathodic Tafel slope of $\mathbf{b_c}$ = -0.153 V/dec. (S.D. 0.030, n=6), which was used in the calculation of the corrosion current density $\mathbf{i_{cor}}$. In view of the shapes of the anodic polarization curves the anodic Tafel slope was considered to be much higher than the cathodic Tafel slope, and the corrosion current density was calculated using the formula

$$i_{cor} = b_c/(2.303\ R_p)$$

The results have been plotted in Fig. 6. Three of the four specimens showed an initial drop in the corrosion current density from the first to the second day of exposure. The corrosion current density remained almost constant after the second day of exposure for all specimens. For the exposure period of 2-26 days the minimum current density was 9.55E-9 A/cm^2, and the maximum was 2.66E-8 A/cm^2. The overall mean corrosion current density for this time period was 1.52E-8 A/cm^2 (S.D. 5.23E-9, n=4).

4.1.6 Comparison of Test Parameters

4.1.6.1 Breakdown potential vs. Corrosion potential: The mean breakdown potential was 0.314 V higher than the mean corrosion potential. The difference was statistically significant at $\alpha = 0.05$ and $\alpha = 0.01$.

4.1.6.2 Repassivation potential vs. Corrosion potential: The mean repassivation potential was not statistically different from the mean corrosion potential (difference of 2 mV) at $\alpha = 0.05$.

4.2 VascuCoil™ Vascular Stents

4.2.1 Potential *vs.* Time

The potential-time variation (Fig. 7) was similar to the behavior of the coronary stents. The mean potential after stabilization was -0.139 V (SCE) (S.D. 0.037, n=3).

4.2.2 Potentiodynamic Anodic Polarization Curves

The five polarization curves (standard scanning rate of 10 mV/min) have been overlayed in Fig. 8. Critical test parameters are listed in Table 5. The polarization curves showed a behavior similar to the coronary stents. The breakdown potential ranged from -0.082 V to 0.026V (SCE). The mean value was -0.027 V (SCE) (S.D. 0.041, n=5).

4.2.3 Repassivation Test Results

The three cyclic polarization curves (performed at the standard scanning rate of 10 mV/min) have been overlayed in Fig. 9. The repassivation potentials are listed in Table 5. The cyclic polarization behavior was similar to that of coronary stents. The repassivation potential ranged from -0.142 V to -0.095V (SCE). The mean value was -0.119 V (SCE) (S.D. 0.024, n=3).

4.2.4 Potentiodynamic Current Density in the Passive State

The potentiodyanmic current density in the passive state was determined at the mean open circuit corrosion potential, i.e., 0.139 V (SCE). The mean passive current density was 6.60E-8 A/cm^2 (S.D. 6.50E-8, n=5).

4.2.5 Comparison of Test Parameters

4.2.5.1 Breakdown potential vs. Corrosion potential: The mean breakdown potential was 0.112 V higher than the mean corrosion potential. The difference was statistically significant at both $\alpha = 0.05$ and $\alpha = 0.01$.

4.2.5.2 Repassivation potential vs. Corrosion potential: The mean repassivation potential was not statistically different from the mean corrosion potential at $\alpha = 0.05$ (the mean repassivation potential was only 0.020 V higher than the mean corrosion potential).

4.3 Carotid Stents

4.3.1 Potential *vs.* Time

Fig. 10 shows a plot of the corrosion potential vs. exposure time for the six specimens. Three of the six showed a substantial short-term instability of the corrosion potential even after the long-term mean value became almost stable, as illustrated in more detail in Fig. 11. The corrosion potential values between 14 and 15 hours of exposure were averaged; the data are shown in Table 6. The means ranged from -0.138 V (SCE) to -0.060 V (SCE). The mean for all six specimens was -0.100 V (SCE) (S.D. 0.032, n=6).

4.3.2 Potentiodynamic Anodic Polarization Curves

The six polarization curves have been plotted in Fig. 12. The behavior was similar to those of the vascular stents. Critical test parameters are listed in Table 6. The breakdown potential ranged from -0.100 V to 0.116V (SCE). The mean value was -0.019 V (SCE) (S.D. 0.084, n=6).

4.3.3 Repassivation Test Results

The repassivation potentials are listed in Table 6. The values ranged from -0.146 to -0.052 V (SCE). The mean repassivation potential was -0.107 V (SCE) (S.D. 0.034, n=6).

4.3.4 Potentiodynamic Current Density in the Passive State

The mean potentiodynamic current density in the passive was determined for each specimen at the previously determined stabilized open circuit corrosion potential (Table 6). The mean value was 7.68E-8 A/cm^2 (S.D. 6.15E-8, n=6).

4.3.5 Comparison of Test Parameters

4.3.5.1 Breakdown potential vs. Corrosion potential: The mean breakdown potential was 0.081 V higher than the mean corrosion potential. The difference was statistically significant at $\alpha = 0.05$ but not at $\alpha = 0.01$.

4.3.5.2 Repassivation potential vs. Corrosion potential: The mean repassivation potential was not statistically different from the corrosion potential at $\alpha = 0.05$ (the mean repassivation potential was 7 mV lower than the mean corrosion potential).

5. DISCUSSION

5.1 General

Laboratory electrochemical corrosion tests of metallic biomaterials and devices attempt to answer the following questions, using a body fluid substitute as the corrosive medium:

- *Under open circuit conditions, is the material inert, actively corroding, or in a passive state?*

  Except for noble metals, most metallic biomaterials are passivating alloys. The two measurements answering the above question are the corrosion potential measurements (using a solution containing dissolved oxygen, i.e., aerated), and anodic polarization measurements (using a solution without dissolved oxygen, i.e., deaerated). Passivity appears on the polarization curve as a region of potential-independent current density.

- *If the material is in a passive state under the open circuit condition* (at the corrosion potential, measured under oxidation conditions simulating the body), *does the passive state break down at some higher potential? If it does, how close is this "breakdown potential" to the corrosion potential on the potential scale? Is the breakdown potential lower or higher than some estimated highest possible electrode potential.*

  The breakdown potential is most commonly determined using a potentiodynamic anodic polarization measurement, in which the potential is scanned in the positive direction and the anodic current density is recorded; a breakdown of passivity is indicated by a sharp increase in current density above a critical potential.

  The highest possible electrode potential for arterial blood is not known, unfortunately. Two values can be used as estimates. A theoretical maximum is likely to be the equilibrium potential for the reaction involving reduction of dissolved oxygen, which is believed to be the major cathodic reaction in body fluids. At the arterial blood conditions, pH 7.4, 37°C, and partial pressure of oxygen 0.1, the equilibrium potential is 0.516 V (SCE). A less stringent criterion is the potential of an inert (platinum) electrode in the synthetic body fluids used in the laboratory tests, measured at the same pH, temperature and partial pressure of oxygen as above. The empirical value of this "redox" or "oxidation/reduction potential (ORP)" for Ringer's solution is about 0.32 V (SCE). If the breakdown potential of the tested material is higher than one or both of the above maxima, it is very unlikely that breakdown of passivity and pitting corrosion would be spontaneously initiated on a clean metal surface in the absence of crevice conditions.

- *If the material exhibits breakdown of passivity, to what value must the potential be lowered to repasssivate the initiated corrosion cell ("repassivation potential")?*

The repassivation potential is determined by reversing the scan during a potentiodynamic anodic polarization measurement at a set value of anodic current density, and measuring the potential at which the anodic current density returns to the passive value. If the reverse scan follows closely the forward scan response, it indicates that no localized corrosion was initiated. If there is a hysteresis loop, however, localized corrosion was induced.

The importance of the repassivation potential is twofold. First, even if the breakdown potential is above the corrosion potential (but below a theoretical maximum), one must consider a possibility that the corrosion potential may reach, at least temporarily, a higher value than in the laboratory measurements, in view of the differences between the laboratory media and the body fluids and body chemistry variations. A potential excursion in the anodic direction may initiate pitting. If the repassivation potential is relatively high, however, the initiated pits would likely repassivate as soon as a change in the conditions returned the potential to a lower value. If the repassivation potential is low, on the other hand, once initiated pits would continue to grow.

Second, the breakdown potential is related only to pitting initiation on an unoccluded metal surface (i.e., in absence of crevice conditions). Under crevice conditions, which may be induced by attached tissues, a localized attack may be initiated even below the breakdown potential, as long as the potential is above the repassivation potential.

Therefore, for complete resistance to crevice corrosion, , the repassivation potential also should be well above the open circuit corrosion potential, ideally above at least one of the aforementioned potential maxima.

- *What is the corrosion rate under the laboratory test conditions?*

For electrochemical corrosion the corrosion rate usually is expressed as a corrosion current density, which can be determined from the measured value of the polarization resistance, or by some other techniques. For passivating materials the corrosion rate initially decreases with time and approaches a stable value, and a meaningful determination requires a long-term test.

If the release of metal ions is an important aspect of the material performance, the corrosion current density can be converted to a rate of the metal ion release using Faraday's law. However, this conversion is based on some assumptions regarding the selectivity of dissolution. For an essentially binary system, such as Ti-Ni, in which the release of one of the components (Ni) is of main concern, a worst case approach dictates all the current density to be considered as due to the release of that component only.

Different electrodes also can be ranked on the basis of the potentidynamic current density in the passive state, at the value of the corrosion potential. The absolute values do not represent stabilized corrosion rate, however, because of the dynamic character of the polarization test.

5.2 Interpretation of the results

5.2.1 CardioCoil™ Coronary Stents

Fig. 3 illustrates that the stents were in a passive state and that the breakdown potential was above the corrosion potential. The mean breakdown potential was about 0.3 V above the mean corrosion potential, which seems to be a safe value, and the two means were statistically different. Fig. 3 also shows that there was a substantial variation in the breakdown potential, and that for a majority of the results the potential difference was closer to 0.2 V, still a reasonably safe difference.

The repassivation test results (Fig. 4), on the other hand, show that when localized corrosion was initiated, repassivation required a potential return to the corrosion potential value, i.e., there was no safety margin with respect to corrosion susceptibility under crevice corrosion condition.

The critical potentials and their relationship are illustrated in Fig. 13, which also includes the corrosion maxima mentioned in section 5.1. Fig. 13 shows that there was no overlap of the 99% confidence intervals for the corrosion potential and the breakdown potential, and the mean of the breakdown potential values was only about 0.1 V below the potential of a platinum electrode (ORP). On the other hand, there was a total overlap of the corrosion potential and repassivation potential intervals. It is concluded that the results indicate a good resistance to pitting initiation, and a marginal resistance to crevice corrosion.

Measurements of the corrosion current density in the passive state (Fig. 6) showed stabilized values ranging from about 0.01 $\mu A/cm^2$ to 0.03 $\mu A/cm^2$, and a mean value of 0.015 $\mu A/cm^2$. These value are typical for corrosion resistant passive alloys. The corresponding nickel dissolution rates (assuming only nickel dissolving) are 0.25 to 0.70 $\mu g/cm^2$- day, mean 0.40 $\mu g/cm^2$- day. These values have to be interpreted by experts in toxicology and immunology. This value also are relevant only in the absence of a localized attack, such as pitting or crevice corrosion.

5.2.2 VascuCoil™ Vascular Stents

Fig. 8 illustrates that the stents were in a passive state. The breakdown potential was above the breakdown potential and the difference between the means was statistically significant. Still, the mean breakdown potential was only about 0.1 V above the mean corrosion potential, which is a relatively small difference. The repassivation test results (Fig. 9), show that to repassivate initiated localized attack required a potential return to the corrosion potential value, i.e., there was no safety margin with respect to corrosion susceptibility under crevice corrosion condition.

The critical potentials and their relationship are illustrated in Fig. 14, which also includes the corrosion maxima mentioned in section 5.1. Fig. 14 shows that in spite of the statistical difference between the means, there was a substantial overlap of the 99% confidence intervals for the corrosion potential and the breakdown potential, and the breakdown potentials were substantially below the open circuit potential of a platinum electrode (ORP). Also there was a total overlap of the corrosion potential and repassivation potential intervals. It is concluded that the results indicate a moderate to marginal resistance to pitting initiation, and a marginal resistance to crevice corrosion.

5.2.3 Carotid Stents

Figs. 10 and 11 show that for at least four of the six specimens the corrosion potential exhibited substantial short-term instability, which might indicate localized corrosion in progress. Fig. 12 shows that although a passive region was observed, the corrosion potentials were very close to breakdown. Statistically, the means of the breakdown potential and the corrosion potential were different on the 95% confidence level but not on the 99% confidence level, indicating a substantial probability of pitting initiation. The repassivation test results showed the mean repassivation potential to be slightly below the mean open circuit corrosion potential, but the difference was not statistically significant.

The critical potentials and their relationship are illustrated in Fig. 15, which also includes the corrosion maxima mentioned in section 5.1. Fig. 15 shows substantial overlap of the 99% confidence intervals for the corrosion potential, breakdown potential, and repassivation potential. The breakdown and repassivation potentials were substantially below the open circuit potential of a platinum electrode (ORP). It is concluded that the results indicate a poor resistance to pitting initiation and crevice corrosion.

5.2.4 Comparison of Results for CardioCoil™ Coronary, VascuCoil™ Vascular, and Carotid Stents

An examination of the results of this study shows that the *In*Stent CardioCoil™ Coronary Stents exhibited corrosion behavior superior to the VascuCoil™ Vascular and Carotid Stents in the resistance to pitting initiation. The carotid stents showed highest susceptibility to pitting. There was little difference in the repassivation behavior for all three types of stents, indicating that under crevice corrosion conditions all three types may suffer some degradation.

The stabilized corrosion rate was determined only for the coronary stents. A comparison of the corrosion current density in the passive state, at the corrosion potential, shows that the means of the dynamic anodic current density were 9.92E-9, 6.60E-8, and 7.68E-8 A/cm^2 for the coronary, vascular and carotid stents, respectively. This is consistent with the ranking of the three types of stents with respect to the susceptibility to pitting, which is, in the order of increasing susceptibility, coronary, vascular, and carotid stents.

6. CONCLUSIONS

1. *In*Stent CardioCoil™ Coronary, VascuCoil™ Vascular, and Carotid Stents have been subjected to electrochemical corrosion tests, under conditions simulating *in vitro* the environment for arterial implants.

2. *In*Stent CardioCoil™ Coronary, VascuCoil™ Vascular, and Carotid Stents exhibited passive behavior under the open circuit corrosion conditions.

3. *In*Stent CardioCoil™ Coronary, VascuCoil™ Vascular, and Carotid Stents exhibited passivity breakdown at potentials above the open circuit corrosion potential. Based on the difference between the breakdown potential and the open circuit corrosion potential the resistance to pitting initiation was judged good for the coronary stents, moderate to marginal for the vascular stents, and poor for the carotid stents.

4. *In*Stent CardioCoil™ Coronary, VascuCoil™ Vascular, and Carotid Stents exhibited repassivation potentials close to the open circuit corrosion potentials. This result indicates a marginal resistance to crevice corrosion.

5. *In*Stent CardioCoil™ Coronary have been tested for long-term corrosion rate. The results for four specimens showed mean corrosion current density of 0.015 $\mu A/cm^2$. The corresponding mean nickel dissolution rate, assuming only nickel dissolving, would be 0.40 $\mu g/cm^2$- day. This value is relevant only for a condition of uniform dissolution, in the absence of a localized attack, such as pitting or crevice corrosion.

Table 1
Test matrix
InStent Coronary Stents

Specimen ID	Corrosion potential	Anodic polarization	Repassivation (slow)	Repassivation (fast)	Cathodic polarization
IN001		X			
IN002		X			
IN003		X			
IN004		X			
IN005		X			
IN006	X	X			
IN007	X	X	X		
IN008	Long-term corrosion potential and rate test				
IN009	Long-term corrosion potential and rate test				
IN010	Long-term corrosion potential and rate test				X
IN011	X	X	X		X
IN012	X			X	X
IN013	X	X	X		X
IN014				X	
IN015	Long-term corrosion potential and rate test				X
IN016				X	
IN017				X	X
IN018					
IN019					
IN020	X			X	

Table 2
Test Matrix
InStent Vascular Stents

Specimen ID	Corrosion potential	Anodic polarization	Repassivation (slow)
IN021	X	X	
IN022		X	
IN023		X	X
IN024	X	X	X
IN025	X	X	X

Table 3
Test Matrix
InStent Carotid Stents

Specimen ID	Corrosion potential	Anodic polarization	Repassivation (slow)
Lot 52	X	X	X
Lot 54	X	X	X
Lot 56	X	X	X
Lot 57	X	X	X
Lot 58	X	X	X
Lot 59	X	X	X

Table 4
Electrochemical Corrosion Test Parameters
InStent Coronary Stents

Parameter	Test Results (Potentials: V (SCE); Current densities: A/cm^2)									Mean	SD	Min	Max
Corrosion potential	-0.122	-0.141	-0.130	-0.095	-0.081	-0.196				-0.128	0.040	-0.196	-0.081
Breakdown potential (slower scan)	0.128	0.111	0.064	0.462	0.133	0.129	0.087	0.255	0.250	0.180	0.125	0.064	0.462
Breakdown potential (faster scan)	0.139	0.124	0.192	0.130	0.394					0.196	0.114	0.124	0.394
Repassivation potential (slower scan)	-0.139	-0.101	-0.133							-0.124	0.020	-0.139	-0.101
Repassivation potential (faster scan)	-0.119	-0.185	-0.130	-0.138	-0.064					-0.127	0.043	-0.185	-0.064
Passive c.d. @ mean corrosion potential (slower scan)	1.32E-08	2.02E-08	1.32E-08	4.99E-09	7.29E-09	8.39E-09	1.00E-08	6.79E-09	5.21E-09	9.92E-09	4.91E-09	4.99E-09	2.02E-08
Passive c.d. @ mean corrosion potential (faster scan)	4.36E-08	2.37E-08	4.06E-08	1.27E-07	3.03E-08					5.30E-08	4.21E-08	2.37E-08	1.27E-07

Table 5
Electrochemical Corrosion Test Parameters
InStent Vascular Stents

Parameter	Test Results (Potentials: V (SCE); Current densities: A/cm^2)					Mean	SD	Min	Max
Corrosion potential	-0.097	-0.165	-0.156			-0.139	0.037	-0.165	-0.097
Breakdown potential (slower scan)	0.026	-0.019	-0.012	-0.082	-0.049	-0.027	0.041	-0.082	0.026
Repassivation potential (slower scan)	-0.142	-0.119	-0.095			-0.119	0.024	-0.142	-0.095
Passive c.d. @ mean corrosion potential (slower scan)	2.06E-08	6.65E-08	5.09E-08	1.76E-07	1.59E-08	6.60E-08	6.50E-08	1.59E-08	1.76E-07

Table 6
Electrochemical Corrosion Test Parameters
InStent Carotid Stents

Parameter	Test Results (Potentials: V (SCE); Current densities: A/cm^2)									
	Lot 52	Lot 54	Lot 56	Lot 57	Lot 58	Lot 59	Mean	SD	Min	Max
Corrosion potential	-0.132	-0.060	-0.112	-0.138	-0.077	-0.083	-0.100	0.032	-0.138	-0.060
Breakdown potential (slower scan)	0.040	0.116	-0.040	-0.098	-0.031	-0.100	-0.019	0.084	-0.100	0.116
Repassivation potential (slower scan)	-0.118	-0.052	-0.124	-0.146	-0.120	-0.083	-0.107	0.034	-0.146	-0.052
Passive c.d. @ mean corrosion potential (slower scan)	3.57E-08	6.37E-08	2.33E-08	1.69E-07	3.16E-08	1.37E-07	7.68E-08	6.15E-08	2.33E-08	1.69E-07

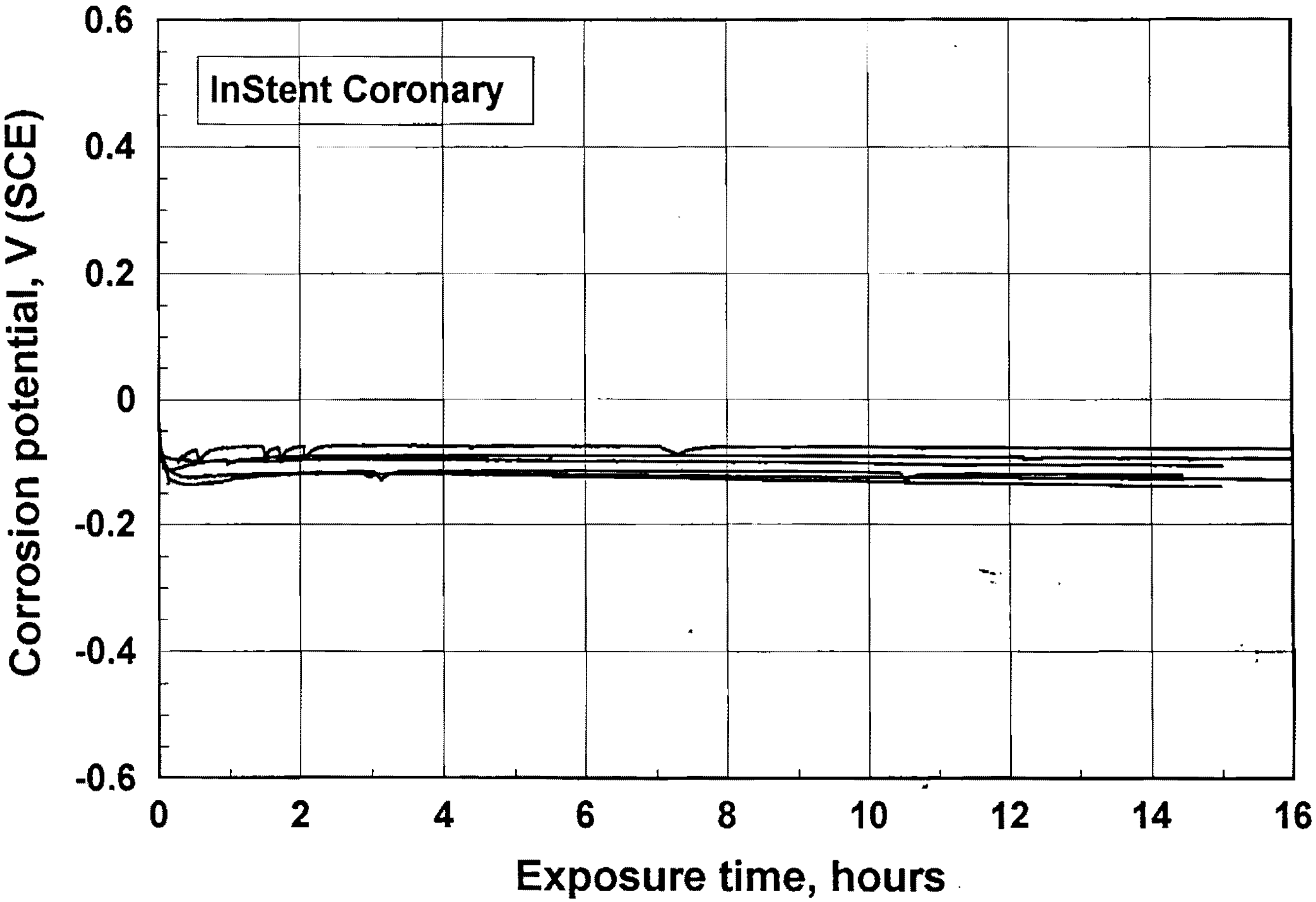

Fig. 1 Corrosion potentials of six *In*Stent CardioCoil™ Coronary Stents in Ringer's solution saturated with 10% oxygen, 5% carbon dioxide, balance nitrogen, at 37°C, pH 7.4.

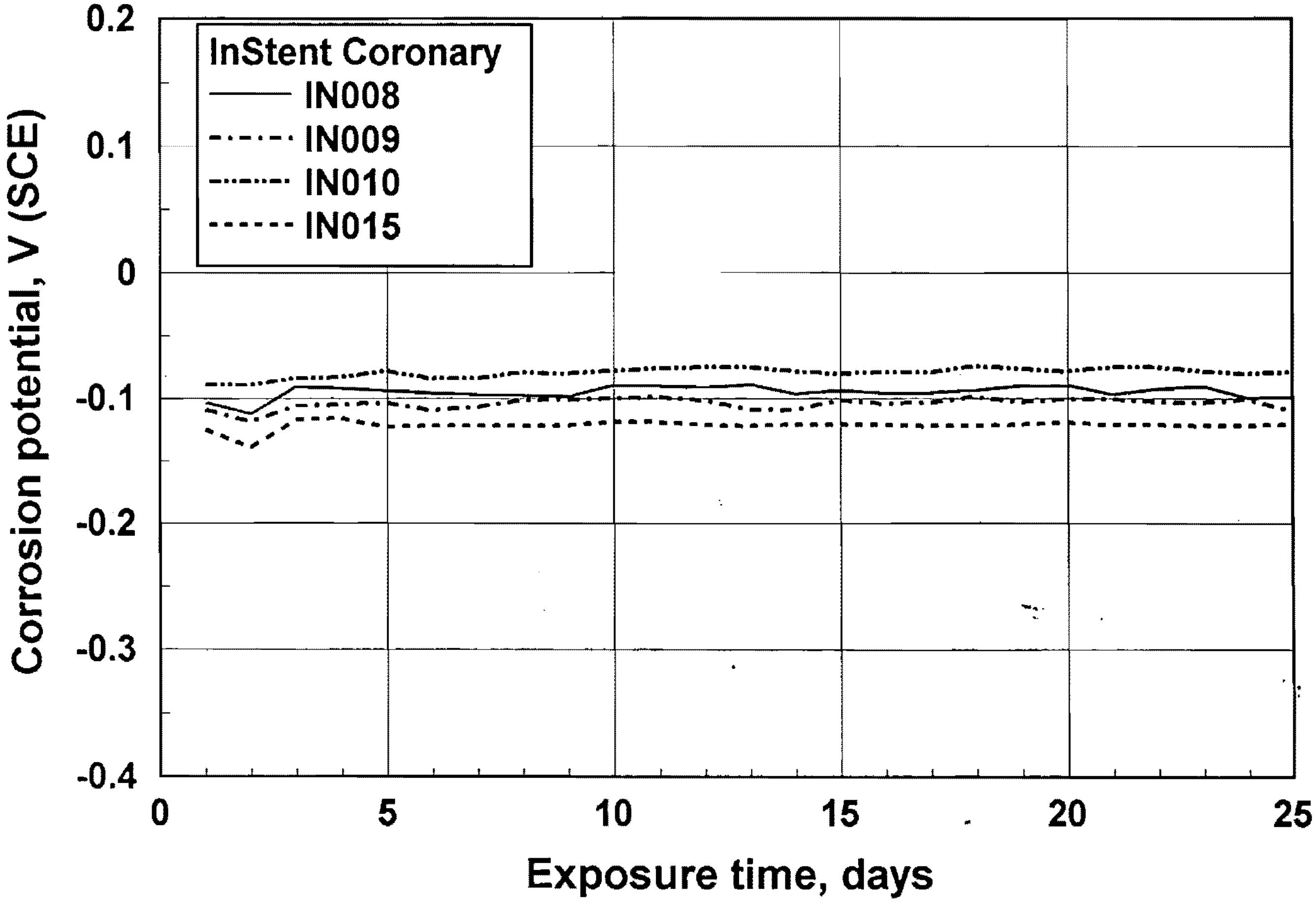

Fig. 2 Long-term corrosion potentials of four *In*Stent CardioCoil™ Coronary Stents in Ringer's solution saturated with 10% oxygen, 5% carbon dioxide, balance nitrogen, at 37°C, pH 7.4.

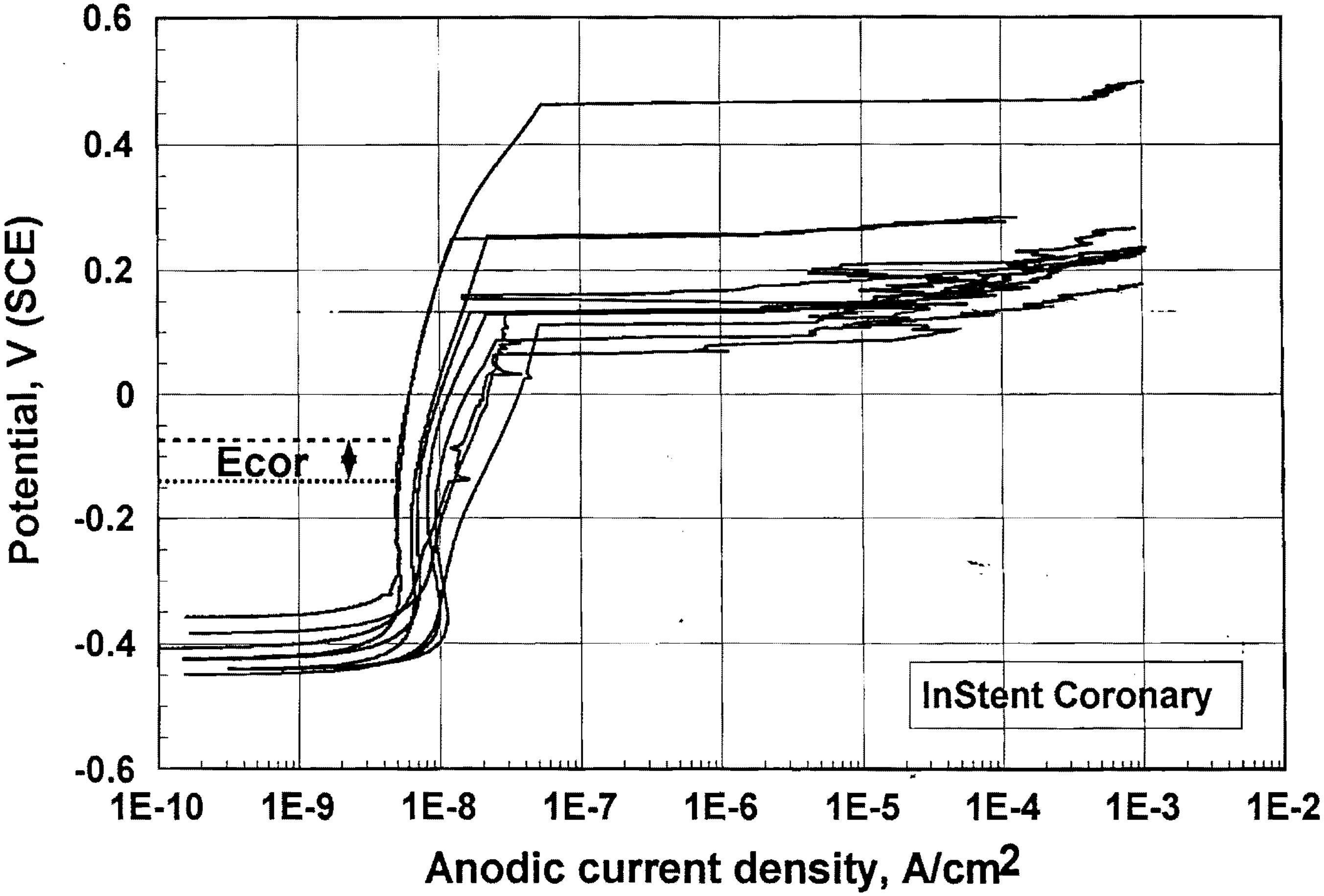

Fig. 3 Potentiodynamic anodic polarization curves for nine *In*Stent CardioCoil™ Coronary Stents in Ringer's solution saturated with nitrogen + 5% carbon dioxide, at 37°C, pH 7.4. Potential scanning rate 10 mV/min.

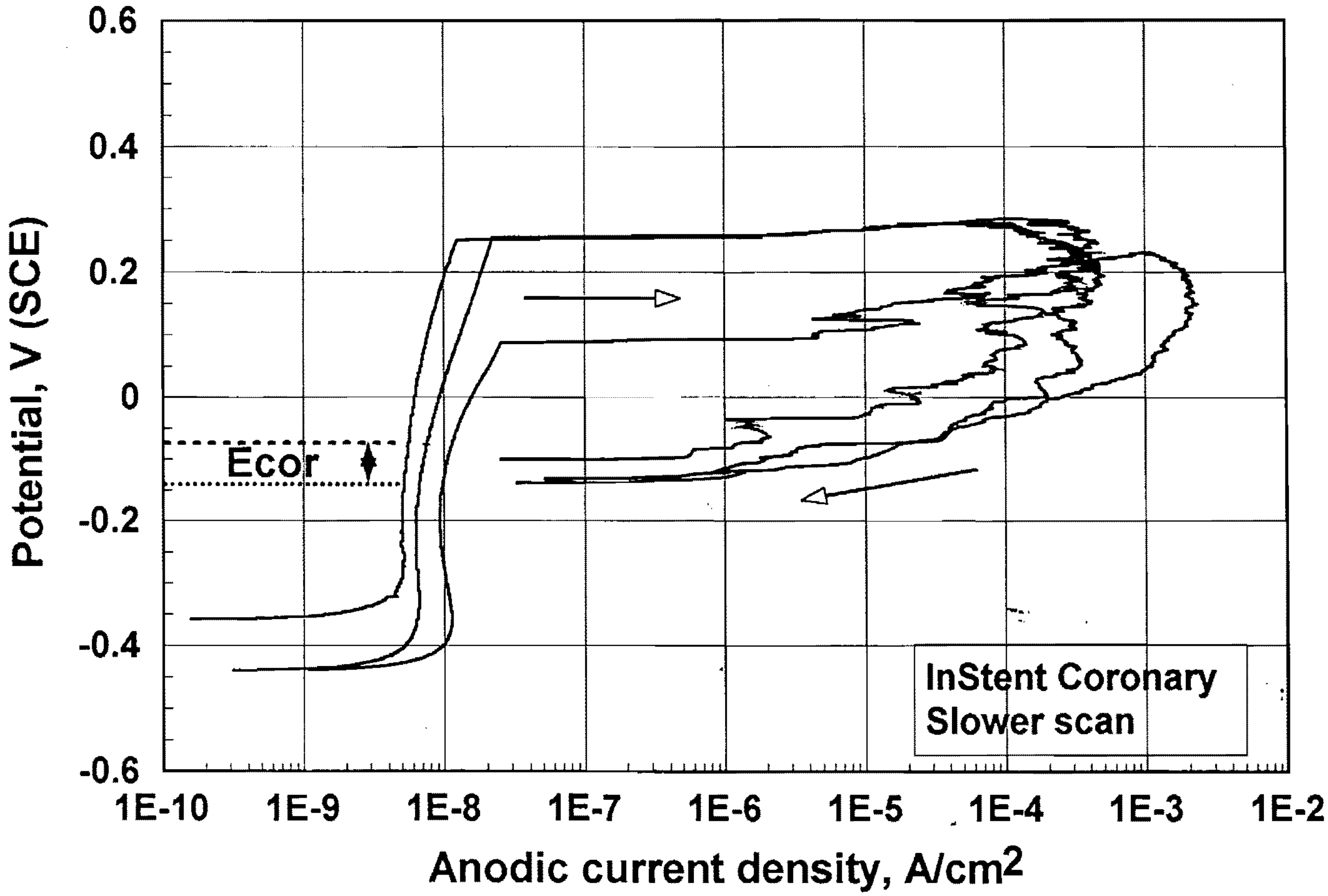

Fig. 4 Results of repassivation polarization measurements for three *In*Stent CardioCoil™ Coronary Stents in Ringer's solution saturated with nitrogen + 5% carbon dioxide, at 37°C, pH 7.4. Potential scanning rate 10 mV/min.

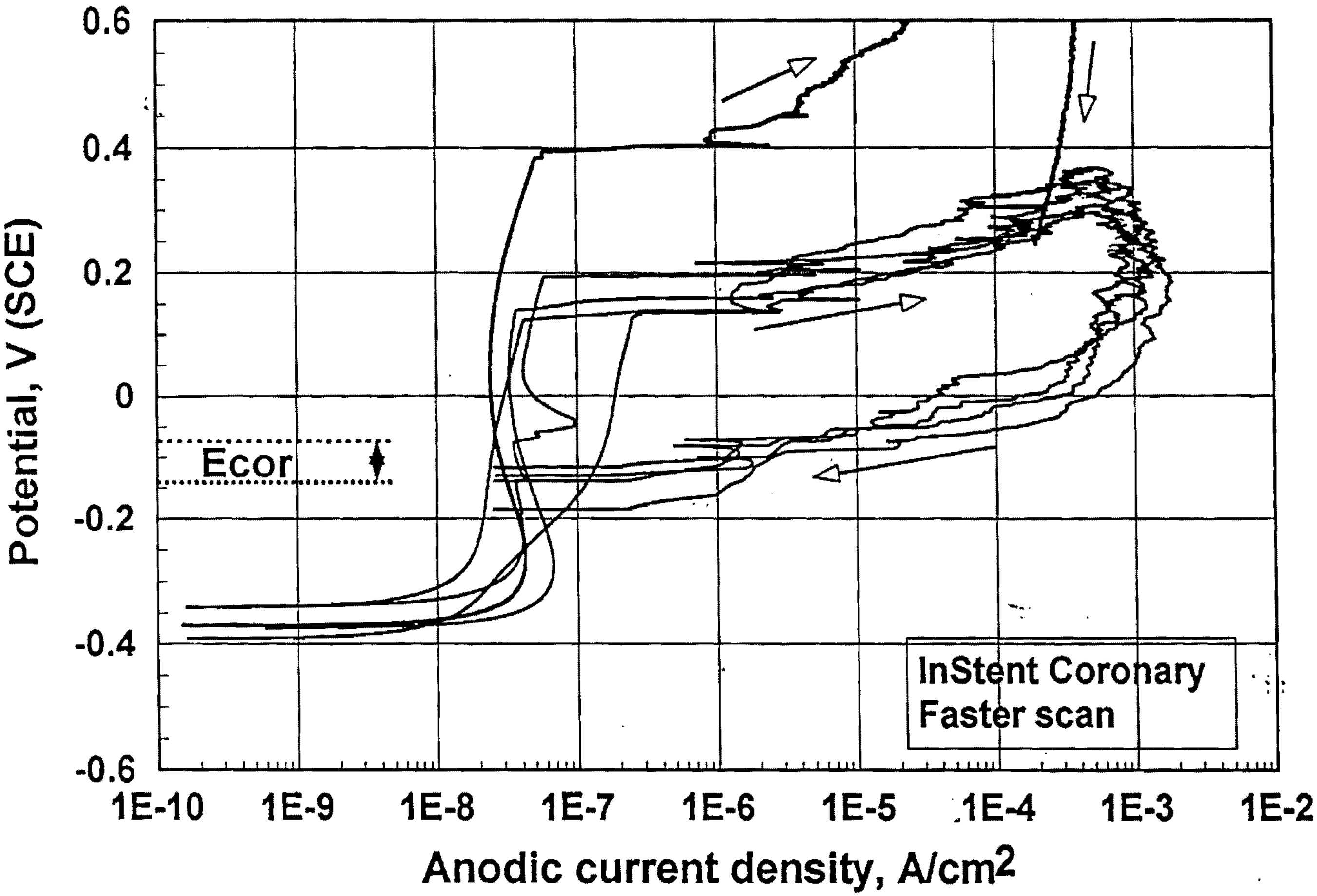

Fig. 5 Results of repassivation polarization measurements for five *In*Stent CardioCoil™ Coronary Stents in Ringer's solution saturated with nitrogen + 5% carbon dioxide, at 37°C, pH 7.4. Potential scanning rate 60 mV/min.

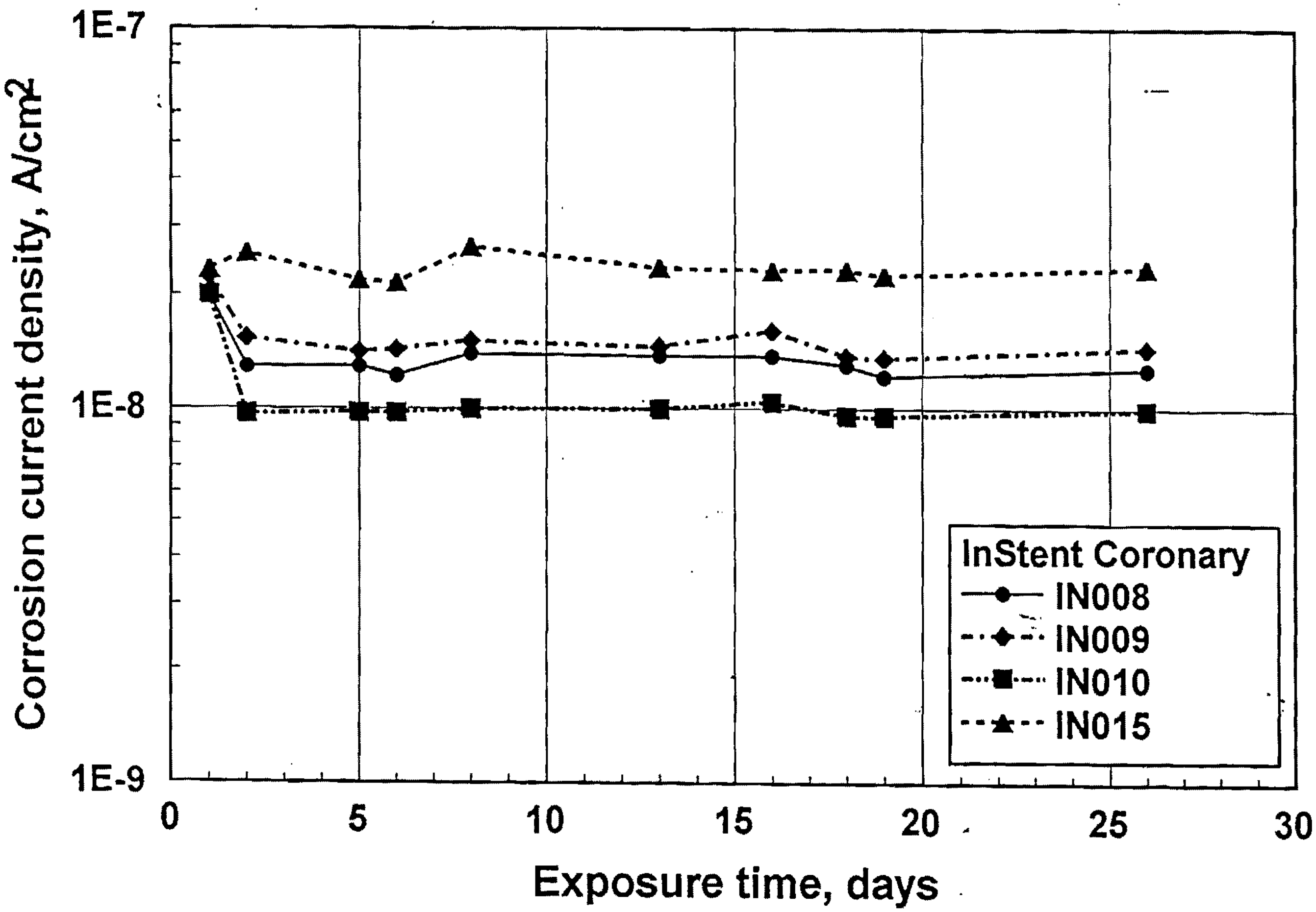

Fig. 6 Long-term corrosion current densities calculated from the results of the polarization resistance measurements for four *In*Stent CardioCoil™ Coronary Stents in Ringer's solution saturated with 10% oxygen, 5% carbon dioxide, balance nitrogen, at 37°C, pH 7.4.

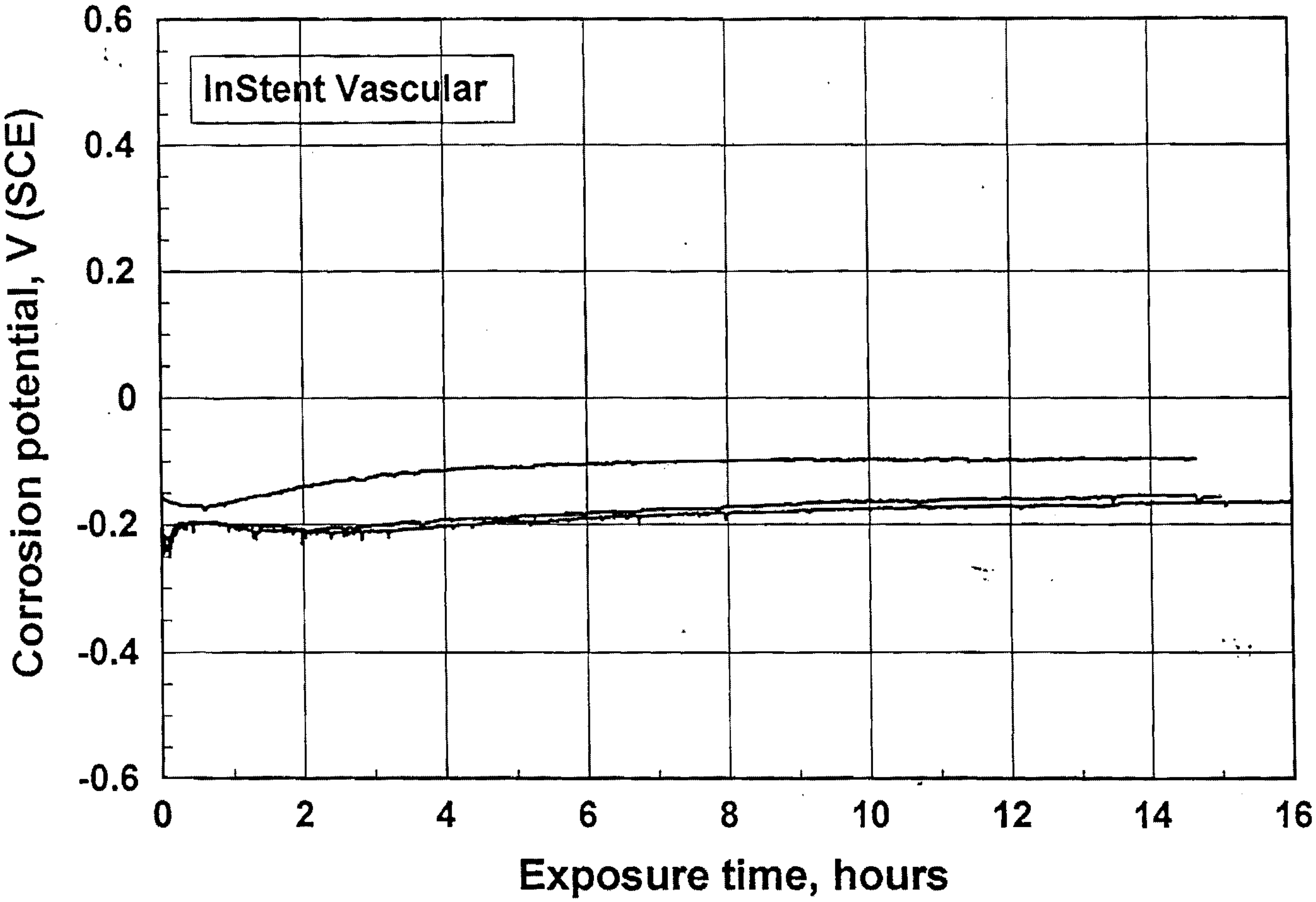

Fig. 7 Corrosion potentials of three *In*Stent VascuCoil™ Vascular Stents in Ringer's solution saturated with 10% oxygen, 5% carbon dioxide, balance nitrogen, at 37°C, pH 7.4.

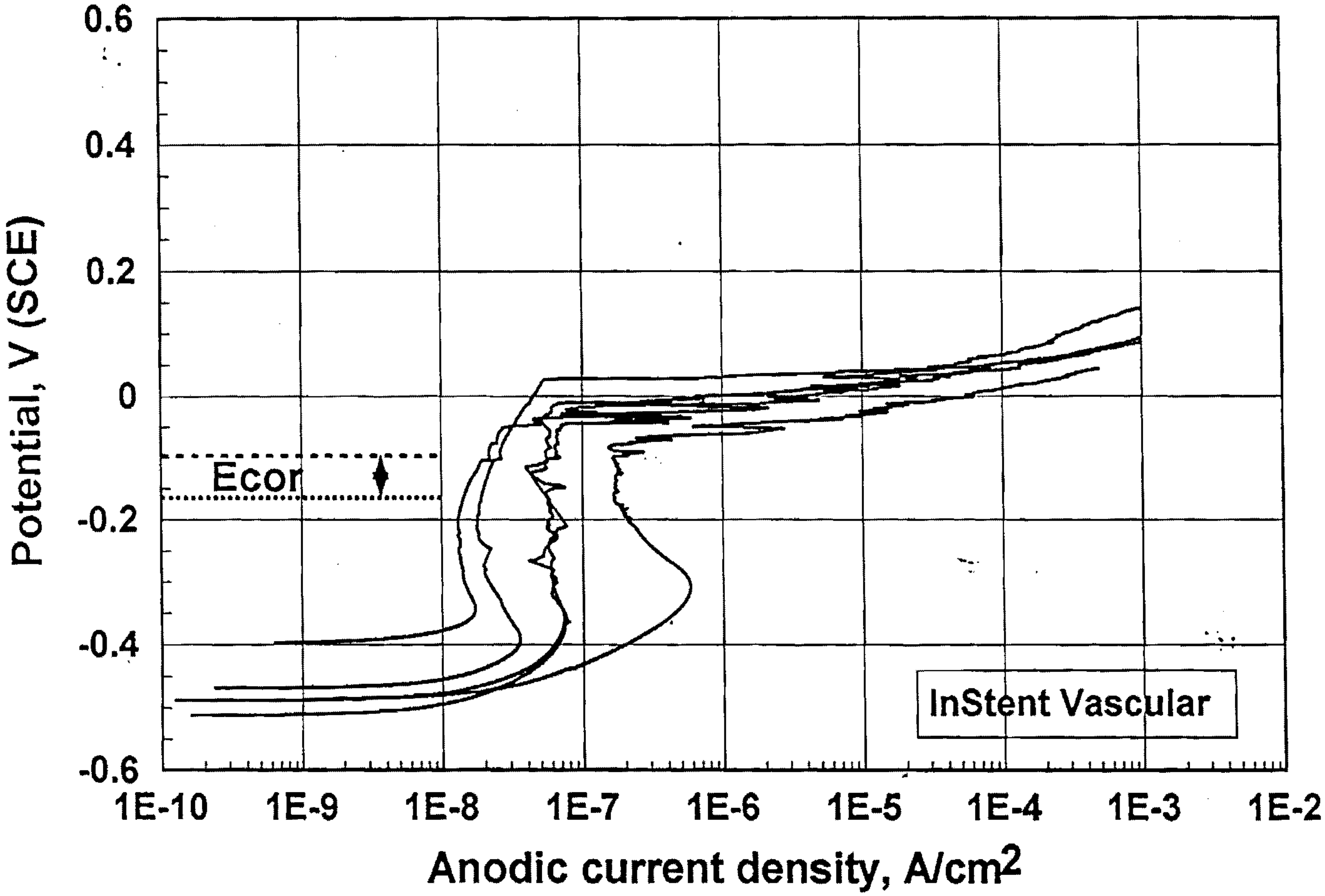

Fig. 8 Potentiodynamic anodic polarization curves for five *In*Stent VascuCoil™ Vascular Stents in Ringer's solution saturated with nitrogen + 5% carbon dioxide, at 37°C, pH 7.4. Potential scanning rate 10 mV/min.

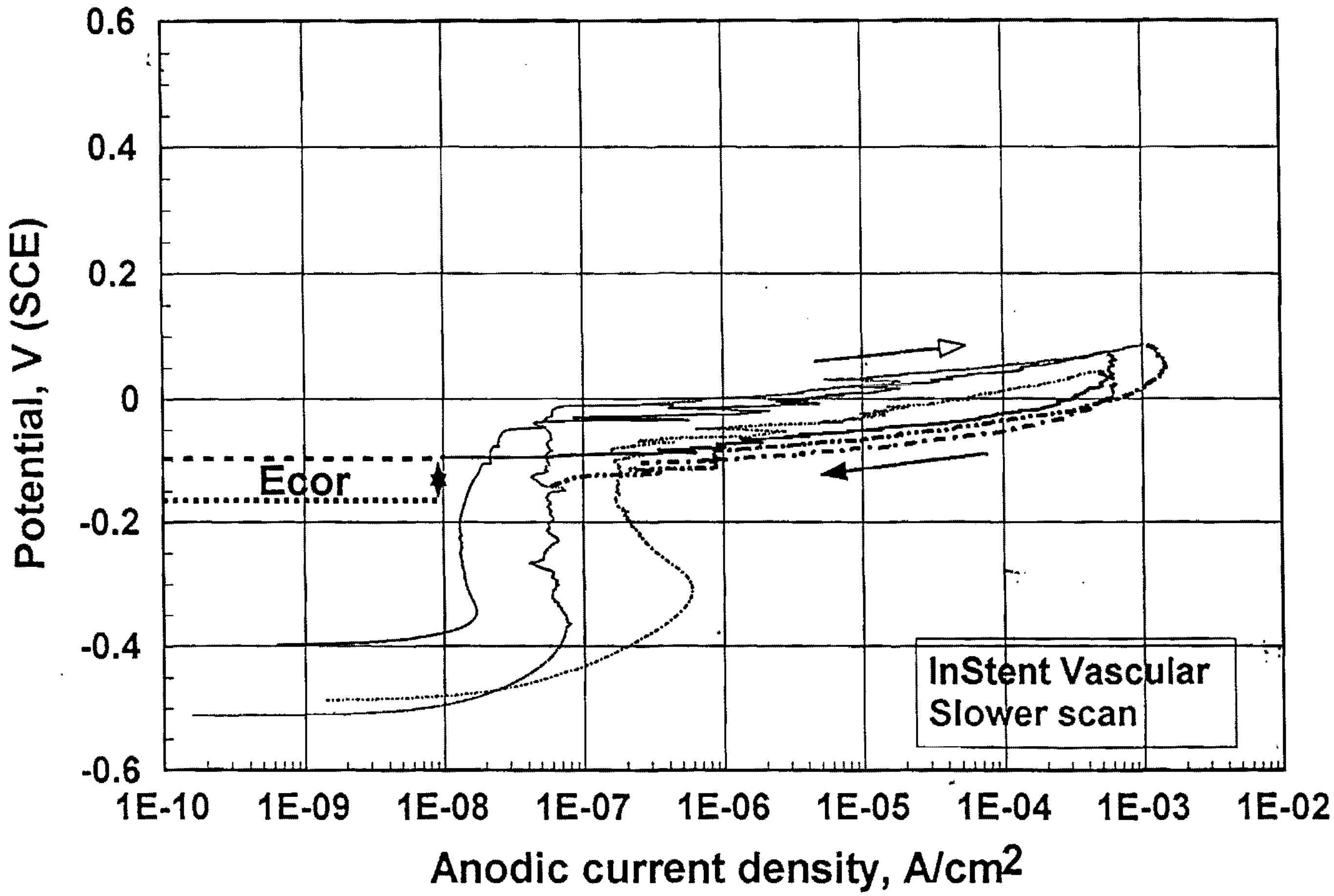

Fig. 9 Results of repassivation polarization measurements for three *In*Stent VascuCoil™ Vascular Stents in Ringer's solution saturated with nitrogen + 5% carbon dioxide, at 37°C, pH 7.4. Potential scanning rate 10 mV/min.

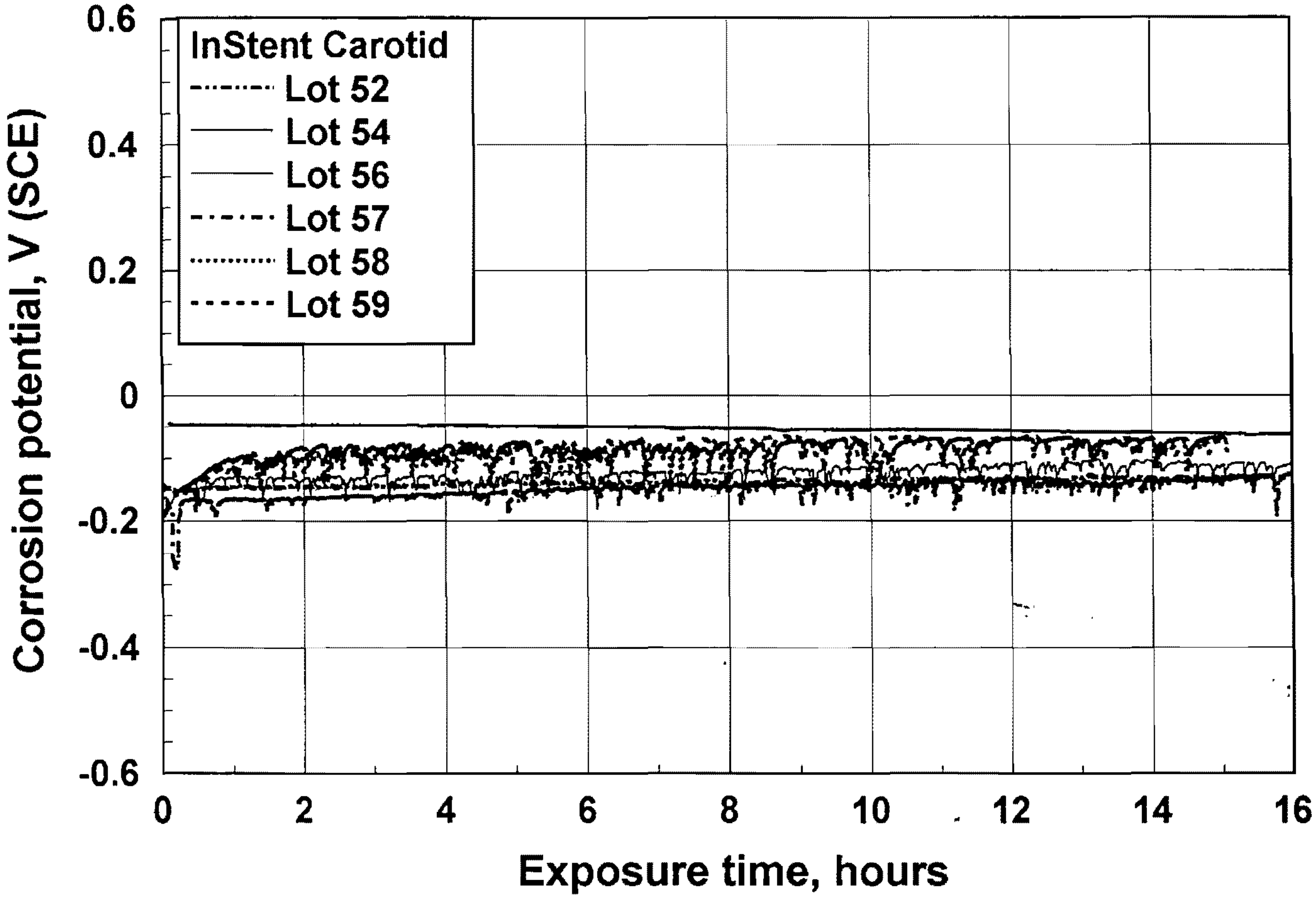

Fig. 10 Corrosion potentials of six *In*Stent Carotid Stents in Ringer's solution saturated with 10% oxygen, 5% carbon dioxide, balance nitrogen, at 37°C, pH 7.4.

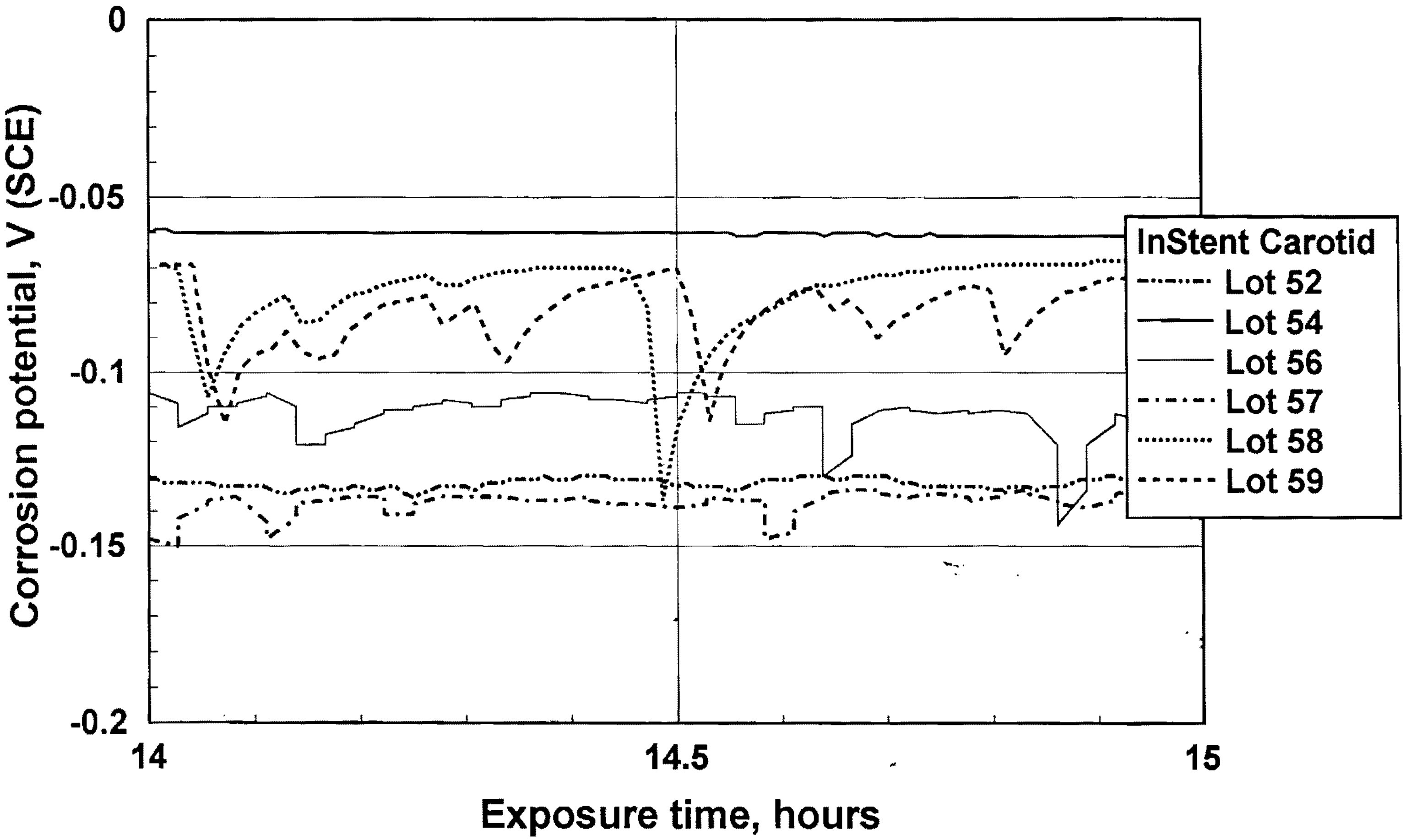

Fig. 11 Corrosion potentials of six *In*Stent Carotid Stents in Ringer's solution saturated with 10% oxygen, 5% carbon dioxide, balance nitrogen, at 37°C, pH 7.4, for exposure period of 14-15 hours.

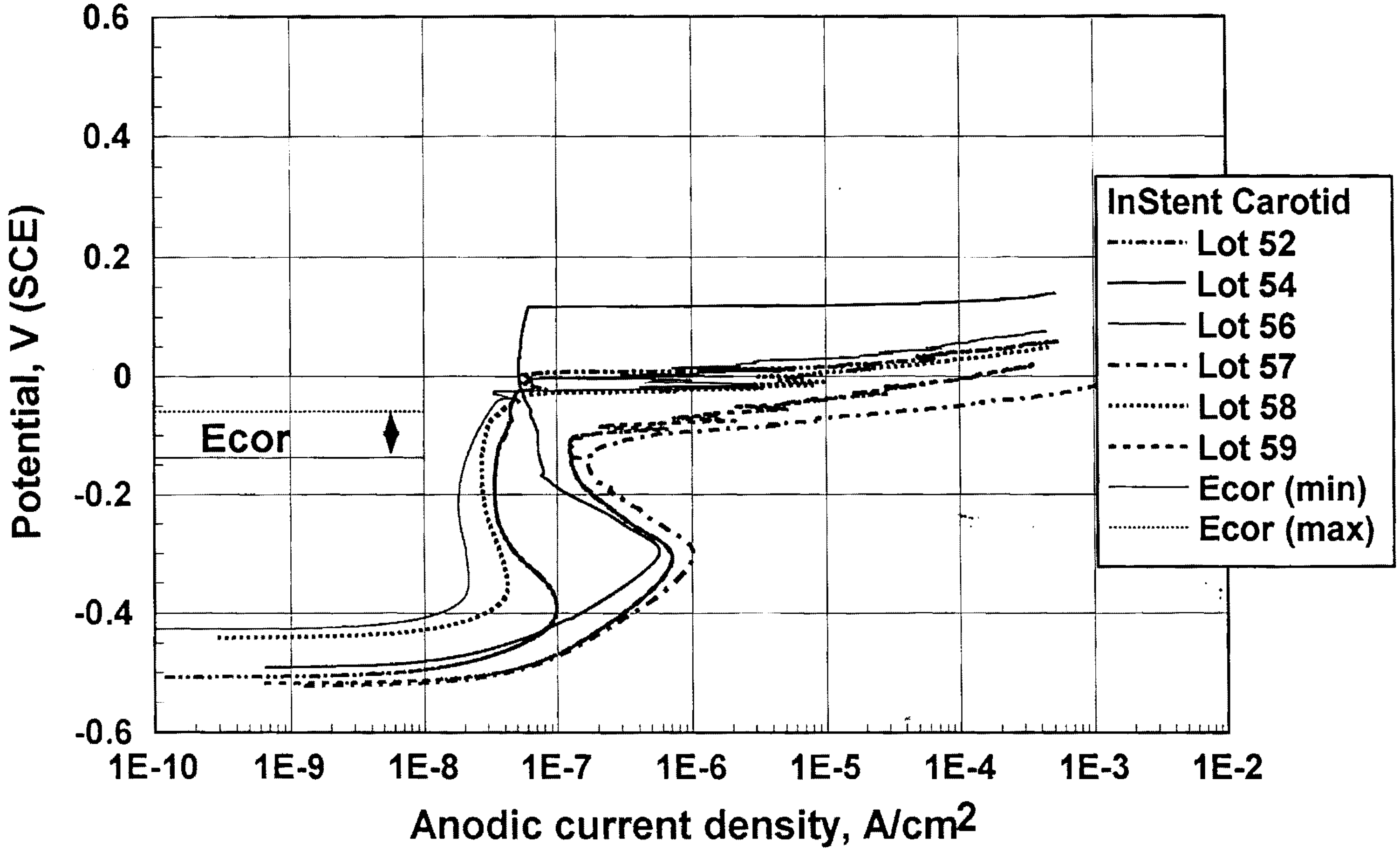

Fig. 12 Potentiodynamic anodic polarization curves for six *In*Stent Carotid Stents in Ringer's solution saturated with nitrogen + 5% carbon dioxide, at 37°C, pH 7.4. Potential scanning rate 10 mV/min.

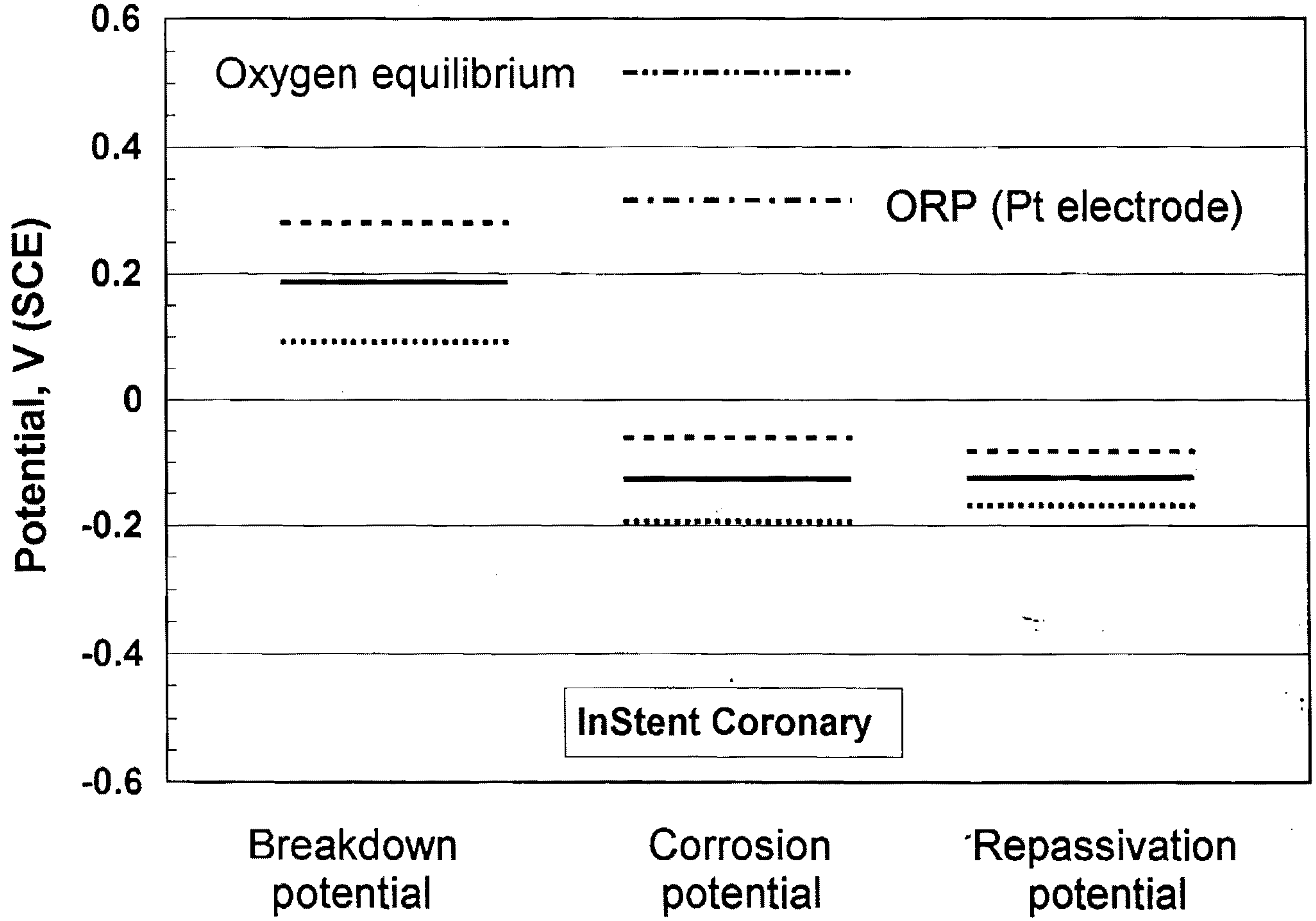

Fig. 13 Critical potentials for *In*Stent CardioCoil™ Coronary Stents in Ringer's solution pH 7.4 at 37°C. Full lines: means. Broken lines: 99% confidence interval. Also indicated are the ORP (oxidation/reduction potential) for Ringer's solution, and the potential of oxygen equilibrium.

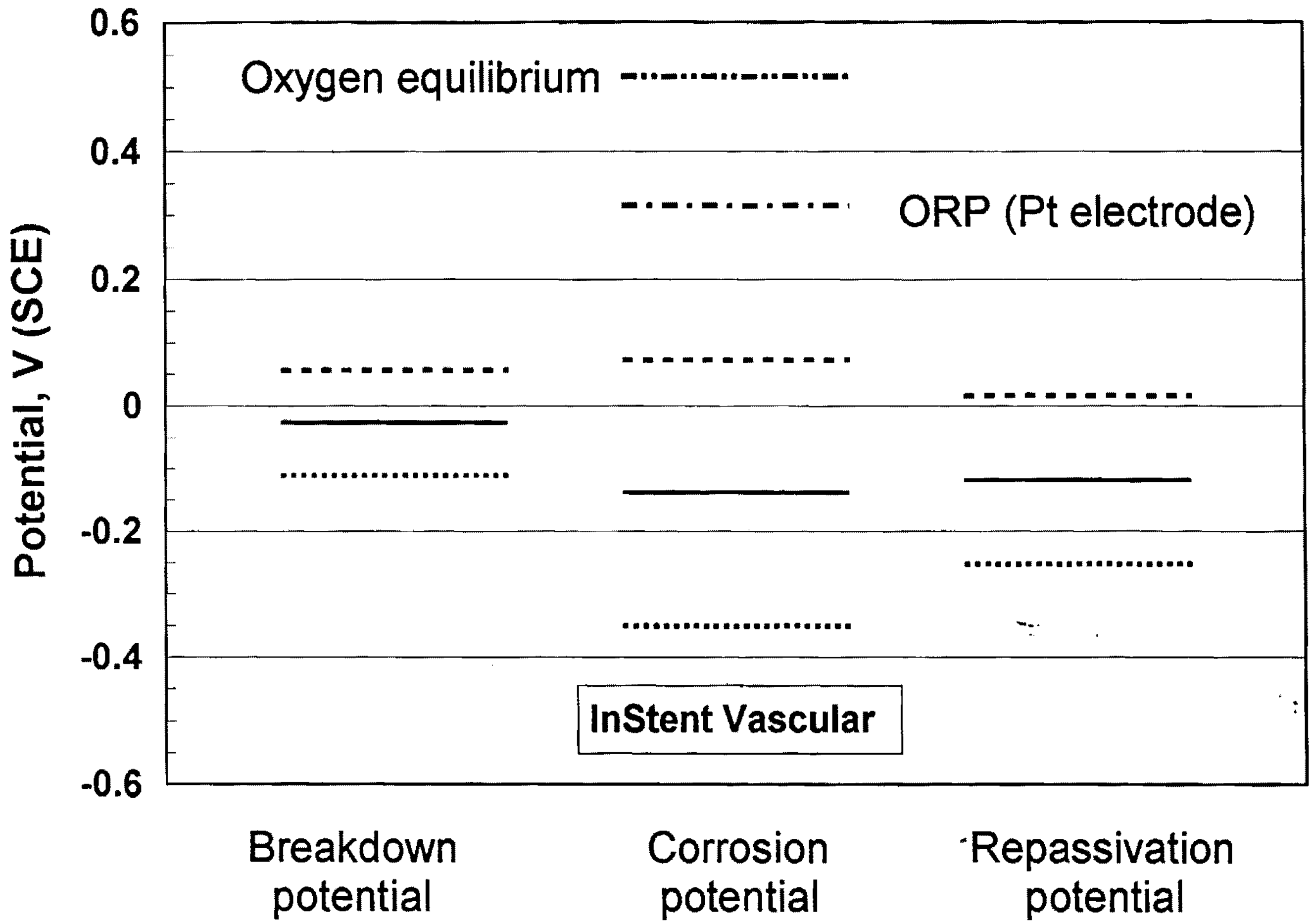

Fig. 14 Critical potentials for *In*Stent VascuCoil™ Vascular Stents in Ringer's solution pH 7.4 at 37°C. Full lines: means. Broken lines: 99% confidence interval. Also indicated are the ORP (oxidation/reduction potential) for Ringer's solution, and the potential of oxygen equilibrium.

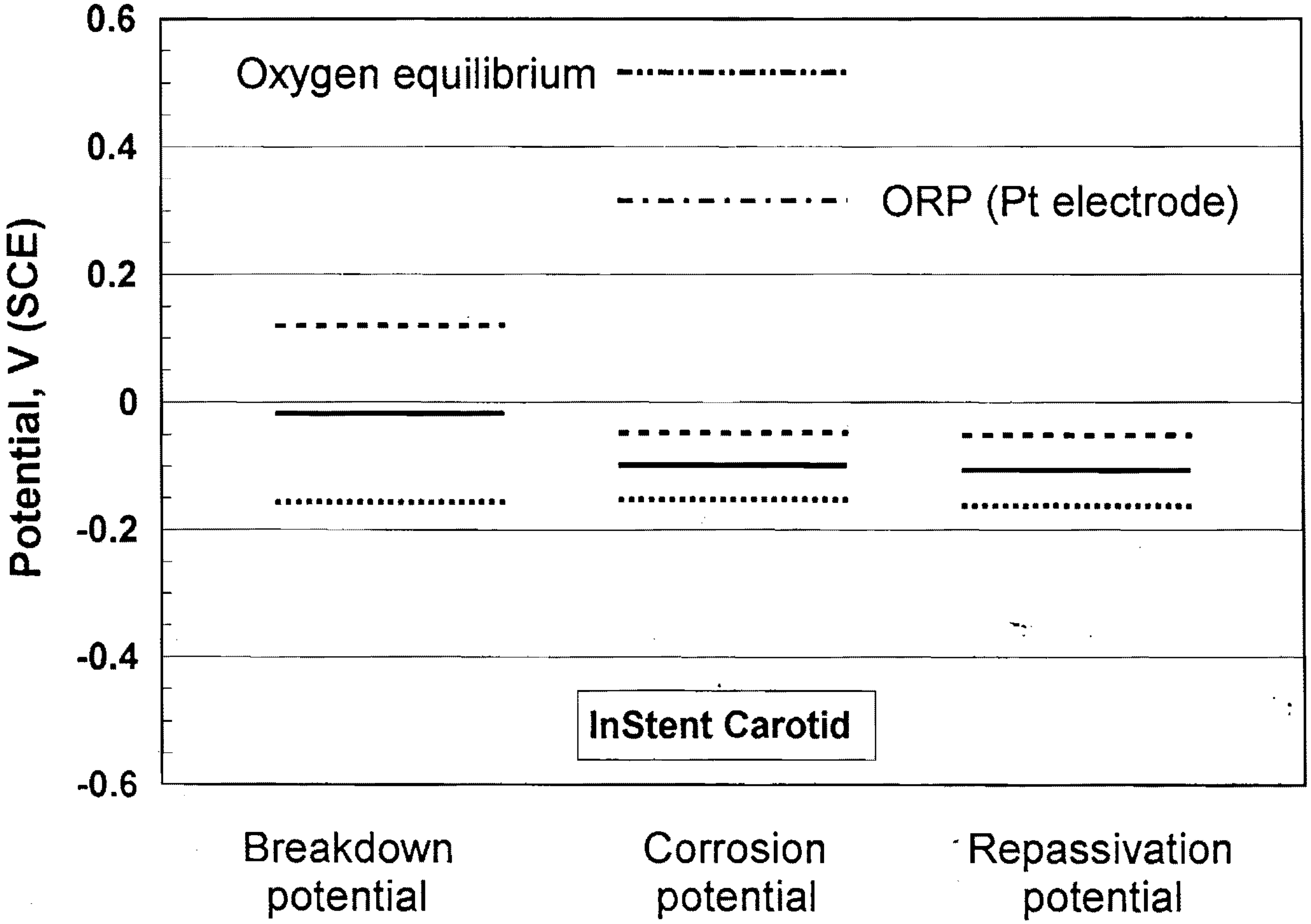

Fig. 15 Critical potentials for *In*Stent Carotid Stents in Ringer's solution pH 7.4 at 37°C. Full lines: means. Broken lines: 99% confidence interval. Also indicated are the ORP (oxidation/reduction potential) for Ringer's solution, and the potential of oxygen equilibrium.