



Design Verification Report - Interconnect, BalSeals

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Development of Networked Implantable Neuroprostheses (NNPS)

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1. Testing at CWRU

1.1. Introduction

1.1.1. Overall Objective

To study the effect of BalSeal design parameters and loading conditions on the BalSeal insertion, extraction and running forces.

1.1.2. General Test Conditions

All tests were conducted at dry, nominal room temperature laboratory conditions unless otherwise mentioned.

1.1.3. Test Equipment

All tests were conducted using a linear actuator of Bose Electroforce Testbench (Bose Corporation, Minnetonka, MN) unless otherwise mentioned.

1.1.4. Load Cell

- Interface 5lb load cell (Interface Inc, Scottsdale, AZ) was used for all the studies. The specifications of the load cell provided by the manufacturer are in Table 1-1.
- Accuracy of the load cell was measured by placing dead weights on the load cell. Maximum error of the load cell was observed to be ± 0.005 N for loads less than 0.5N and ± 0.05 N for loads 0.5 to 9 N (Figure 1-1 & Figure 1-2).

Accuracy – (Max Error)	
Nonlinearity	$\pm 0.05\%$ Full scale (± 0.01 N)
Hysteresis	$\pm 0.05\%$ Full scale (± 0.01 N)
Non-repeatability	$\pm 0.03\%$ RO (± 0.007 N)

Table 1-1 Accuracy of Interface 5lb load cell

Nonlinearity The algebraic difference between OUTPUT at a specific load and the corresponding point on the straight line drawn between MINIMUM LOAD and MAXIMUM LOAD.

Hysteresis The algebraic difference between OUTPUT at a given load descending from MAXIMUM LOAD and OUTPUT at the same load ascending from MINIMUM LOAD

Non-repeatability The maximum difference between OUTPUT readings for repeated loadings under identical loading and environmental conditions

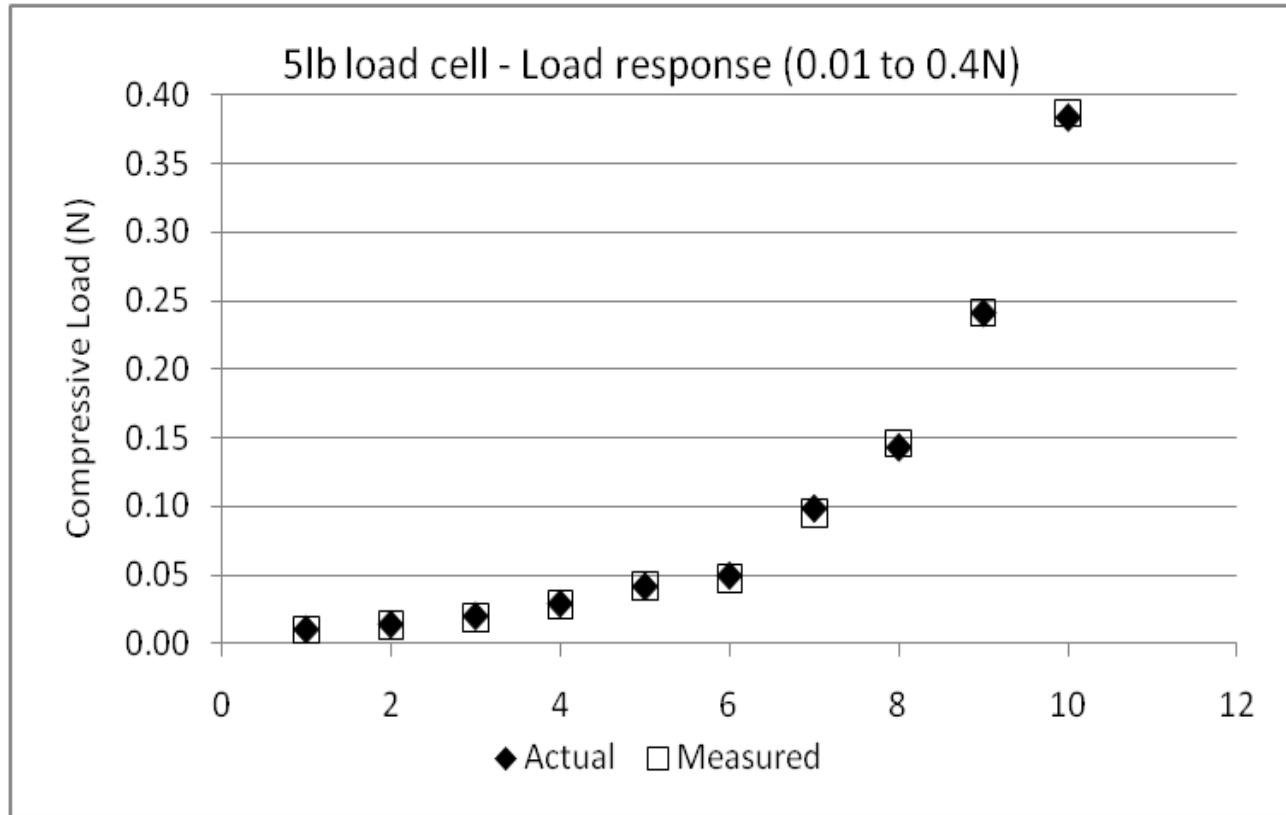


Figure 1-1 Interface 5lb load cell response

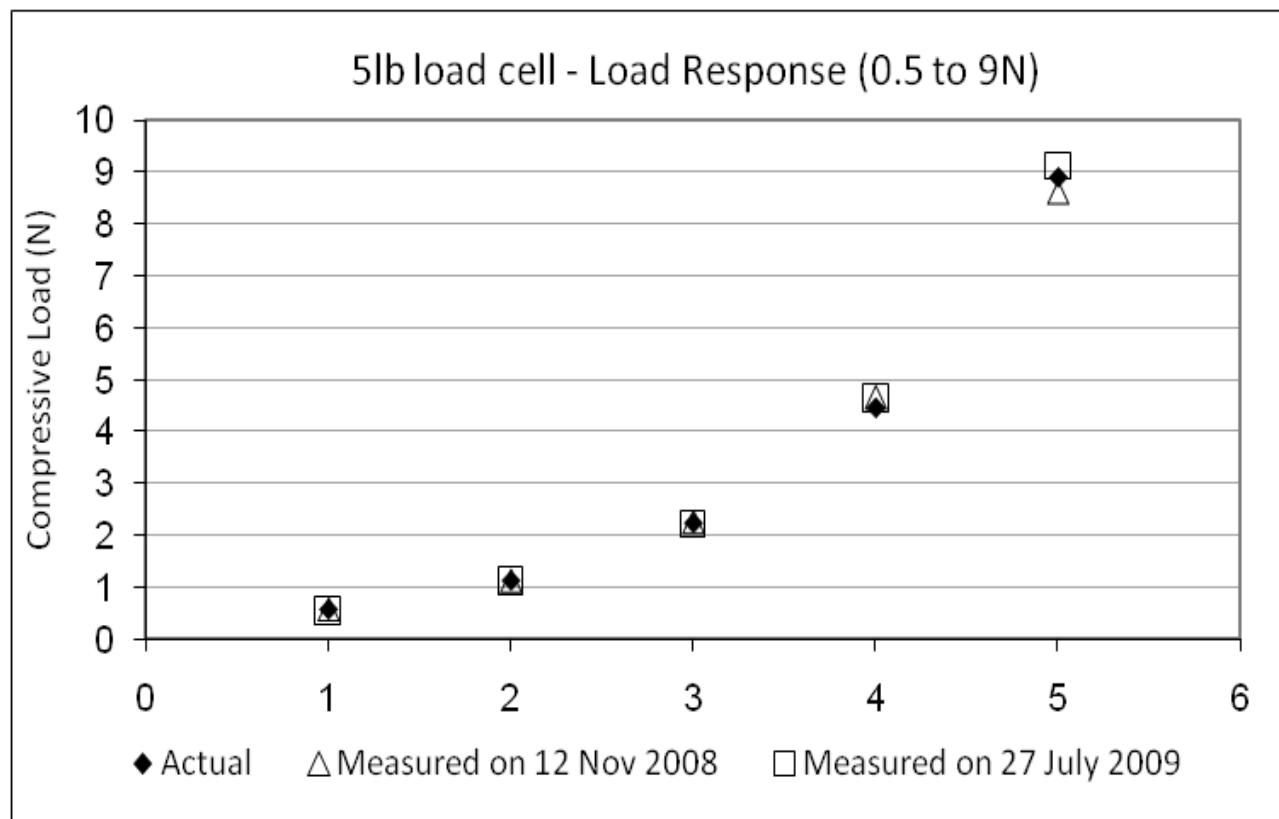


Figure 1-2 Interface 5lb load cell response

1.2. Definitions

Breakout Force: Definition used by BalSeal Engineering Inc. It is the maximum force in the first 20% of the ID Gage travel in to the Balseal.

Insertion Force: Force required to insert a straight circular pin with chamfered end into the BalSeal. For grooved pin insertion force denotes the force required to get the BalSeal off the groove in one direction.

Extraction Force: Force required to get the BalSeal off the groove in the opposite direction.

Running Force: Force required to move the BalSeal on a circular pin.

Balseal ID: Balseal spring inner diameter. It is measured from the SEM image of the Balseal by inscribing a circle that touches most part of the spring.

1.3. Data Capture

- Insertion and extraction forces are measured as the peak force as shown in
-
-
- Figure 1-3.
- Running force is calculated as the average force for a pin travel of 3 mm as shown in

Figure 1-3 after the first 0.5mm travel.

- Typically the running force data has a scatter of $\pm 0.025\text{N}$ as shown in
-
-
- Figure 1-3 inset.

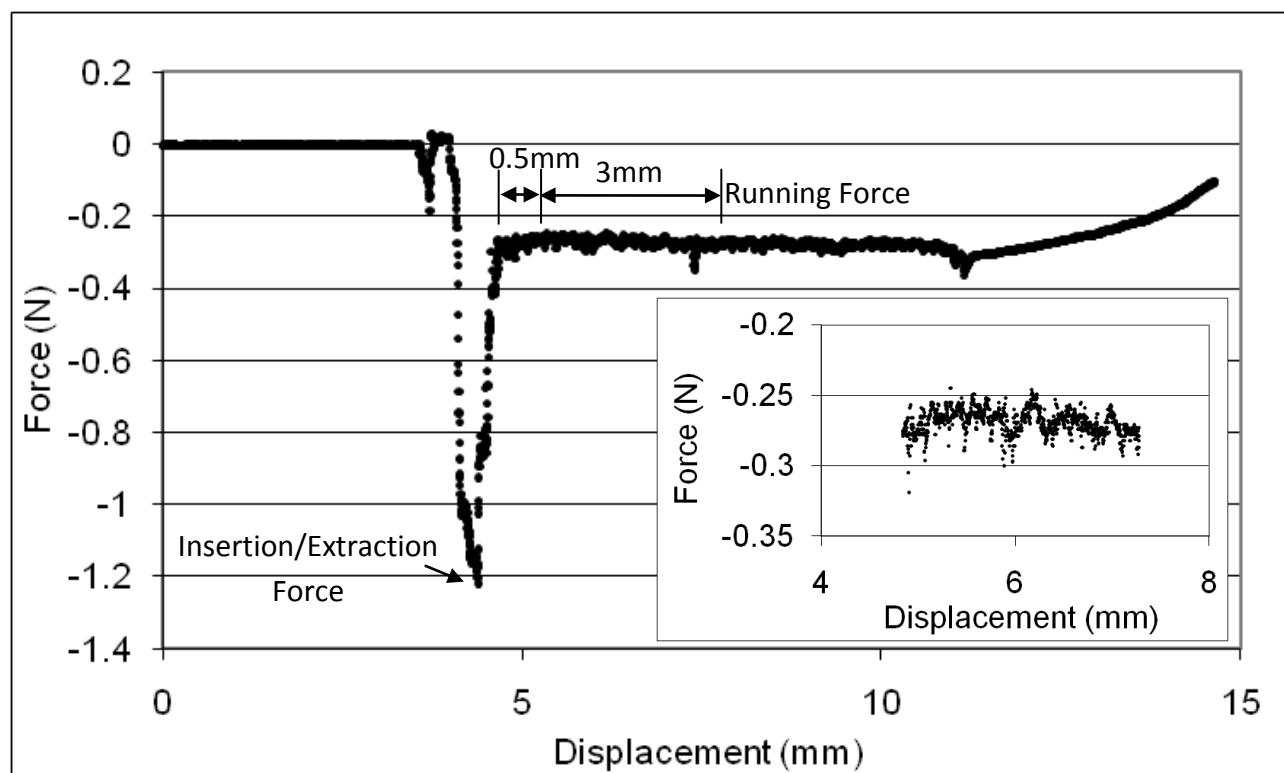


Figure 1-3 Typical Force vs. Displacement response for a straight pin insertion in to a BalSeal.

2. Effect of Groove Width on BalSeal Insertion Forces

2.1. Dates performed

May 2009 - June 2009

2.2. Objective

To study the effect of groove width on BalSeal insertion forces.

2.3. Materials

- Three BalSeals, BalSeal-0, BalSeal-1, BalSeal-2 were used in this study (Table 2-1).
- BalSeal-0 was inserted over the test pin manually many times by different people before this study. BalSeal-1 and BalSeal-2 were tested as received from Ardiem Medical Inc, Indiana, PA (referred to as 'Ardiem' hereafter in this report).
- A test pin of 50mil diameter with six grooves of different groove widths and 45° chamfer on both sides was received from Ardiem. The test pin surface appeared rough. Test pin drawing and magnified views of the chamfers are shown in Appendix 1.

BalSeal #	Revision	Spring ID (mil)	No of coils	Notes
BalSeal-0	A/B	35	32	Spring ID measured after testing
BalSeal-1	A/B	34	31	Spring ID measured before testing
BalSeal-2	A/B	35	33	Spring ID measured after testing

Table 2-1 BalSeals used in this study

2.4. Test Procedure

1. Attach a pin vise to the linear actuator and grip the test pin using a pin vise (Figure 2-1 & Figure 2-2).
2. Insert a BalSeal on the test pin and leave it near groove I (Figure 2-2).
3. Attach a long acrylic tube on the opposite side and make sure it is aligned with the test pin (Figure 2-1).
4. Start data acquisition (Sampling rate = 100 to 400Hz) to record load (using Interface 5lb load cell) and actuator displacement.
5. Move the actuator [Test speed = 0.85mm/sec (2in/min)] such that the BalSeal falls into the groove and climbs up.
6. Repeat the same procedure for the other grooves in the order: groove II, III, IV, V and VI.
7. Repeat testing over all the six grooves two more times.
8. For BalSeal-1, three additional trials of force data was obtained by testing over the grooves in the reverse order i.e. VI, V, IV, III, II, I.
9. BalSeals were examined in the ESEM (FEI Quanta 200 3D, FEI, Hillsboro, OR) before and after testing.

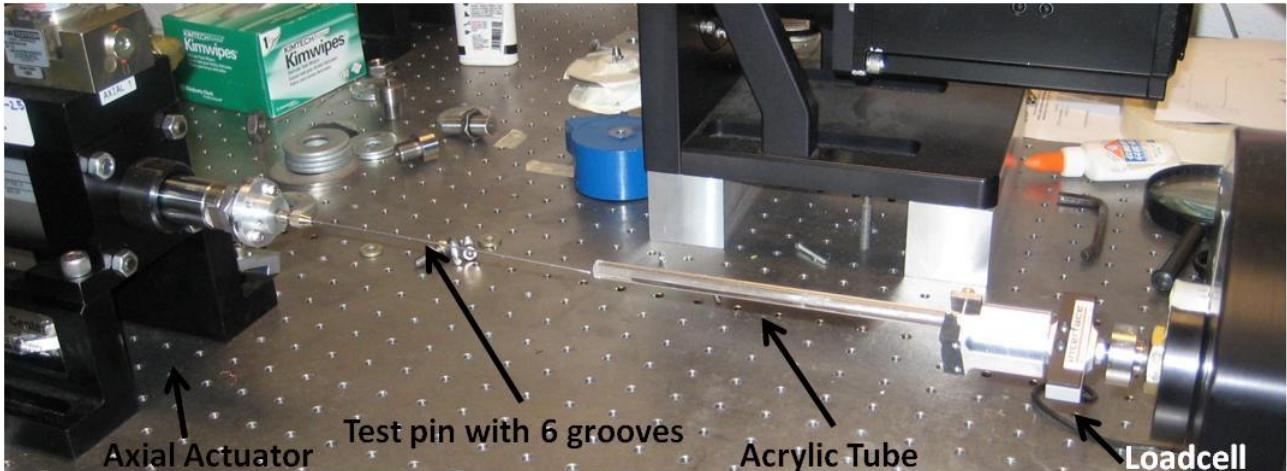


Figure 2-1 Test Setup

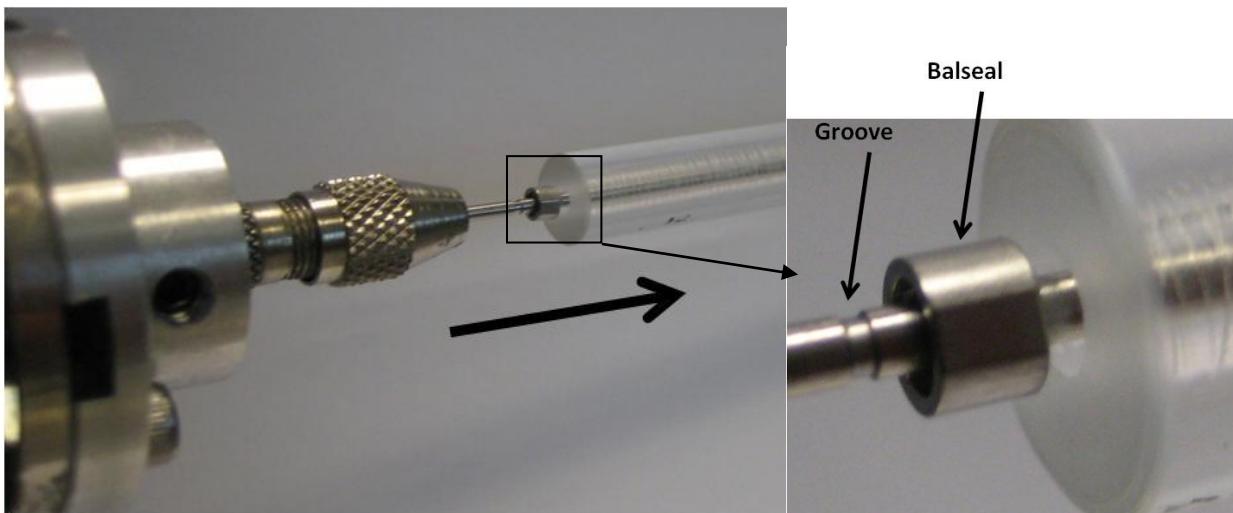


Figure 2-2 Test Setup

2.5. Results

1. A typical load-displacement curve is shown in Figure 2-3. While the BalSeal is moving on the 50mil diameter of the test pin a running force of 0.2N was measured. As the BalSeal falls into the groove, the load cell does not see any load for a brief moment and then the load shoots up as the BalSeal is driven up the chamfer of the groove. (Note: BalSeal is not attached to the acrylic tube; it is free to move on the test pin).
2. Insertion force data for the three BalSeals on different grooves are presented below in Table 2-2 while the average insertion force values for BalSeal-1 and BalSeal-2 are re-presented in Figure 2-4 and Figure 2-5. Trial 1 data is not plotted in the figures.
3. Insertion force for both BalSeal-1 and BalSeal-2 followed similar trend with increase in groove width.
4. Running force on the 50mil diameter of the test pin was about 0.2N for all the BalSeals.
5. Reversing the order of grooves did not significantly change the force trend; however insertion forces were reduced (Figure 2-6). This may be due to the asymmetry of chamfers.
6. SEM images of the BalSeals before and after testing reveal slight wear of the BalSeal spring due to testing. (Appendix 1)

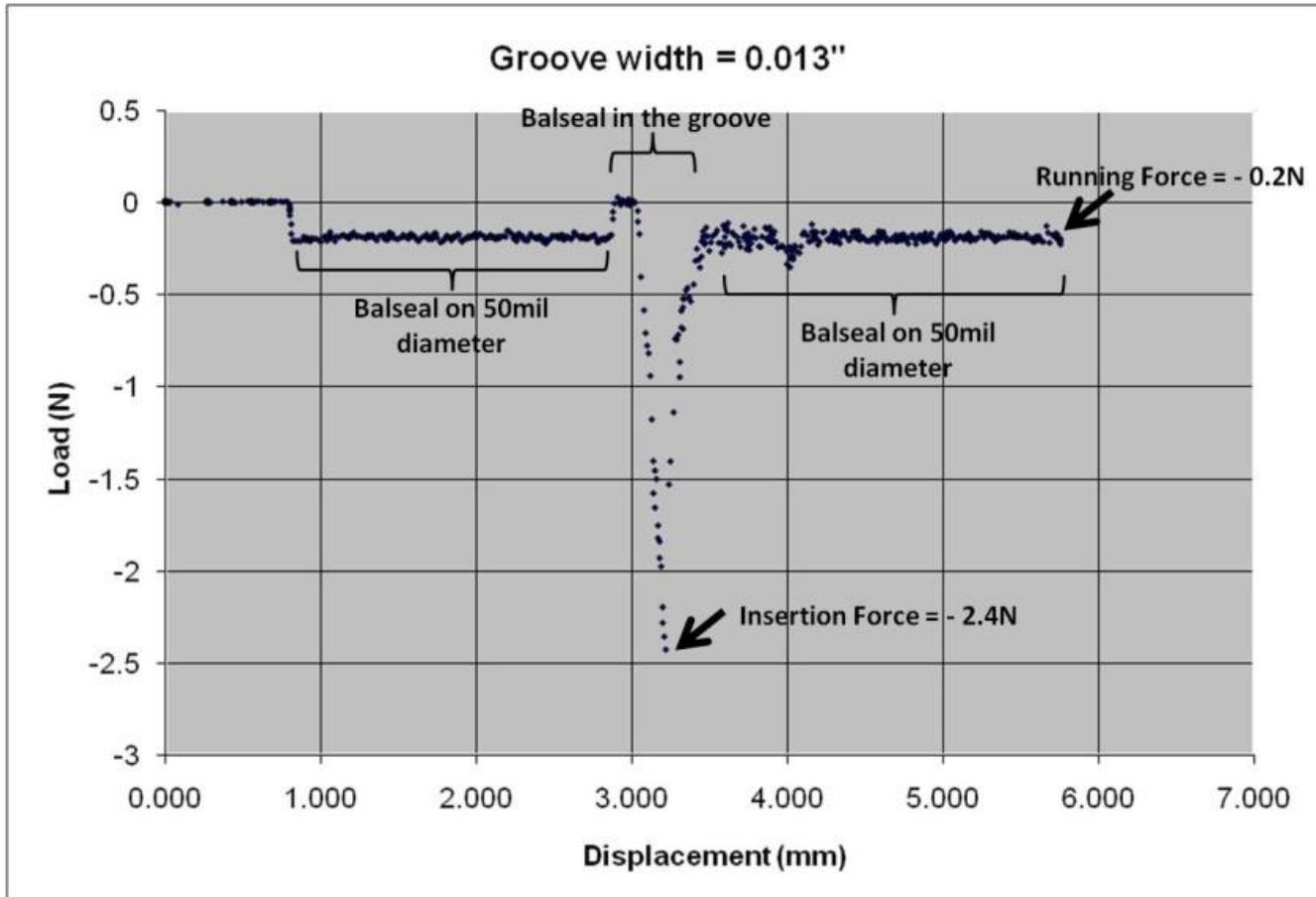


Figure 2-3 Typical load – displacement curve

Groove	Width (Inch)	BalSeal-0	BalSeal-1				BalSeal-1: Reverse test order				BalSeal-2			
		Trial-1	Trial-1	Trial-2	Trial-3	Average	Trial-1	Trial-2	Trial-3	Average	Trial-1	Trial-2	Trial-3	Average
		(N)	(N)	(N)	(N)	(N)	(N)	(N)	(N)	(N)	(N)	(N)	(N)	(N)
I	0.013	2.4	2.1	2.2	1.4	1.8	1.8	1.6	1.4	1.5	2.3	2.1	2.2	2.2
II	0.014	2.3	2.4	3.1	2.1	2.6	1.8	1.7	1.4	1.5	2.6	2.4	2.3	2.4
III	0.015	2.1	1.7	1.5	1.6	1.6	1.5	1.3	1.3	1.3	1.4	1.6	1.3	1.5
IV	0.017	1.9	1.7	1.5	1.4	1.5	1.3	1.3	1.2	1.3	1.6	1.6	1.5	1.6
V	0.021	1.6	1.8	1.9	1.9	1.9	1.6	1.4	1.3	1.3	2.9	1.9	1.7	1.8
VI	0.026	2	1.5	1.5	-	1.5	1.7	1.4	1.4	1.4	1.5	1.4	1.3	1.4

Table 2-2 BalSeal Insertion Force. Trial-1 data is omitted in calculating the average forces.

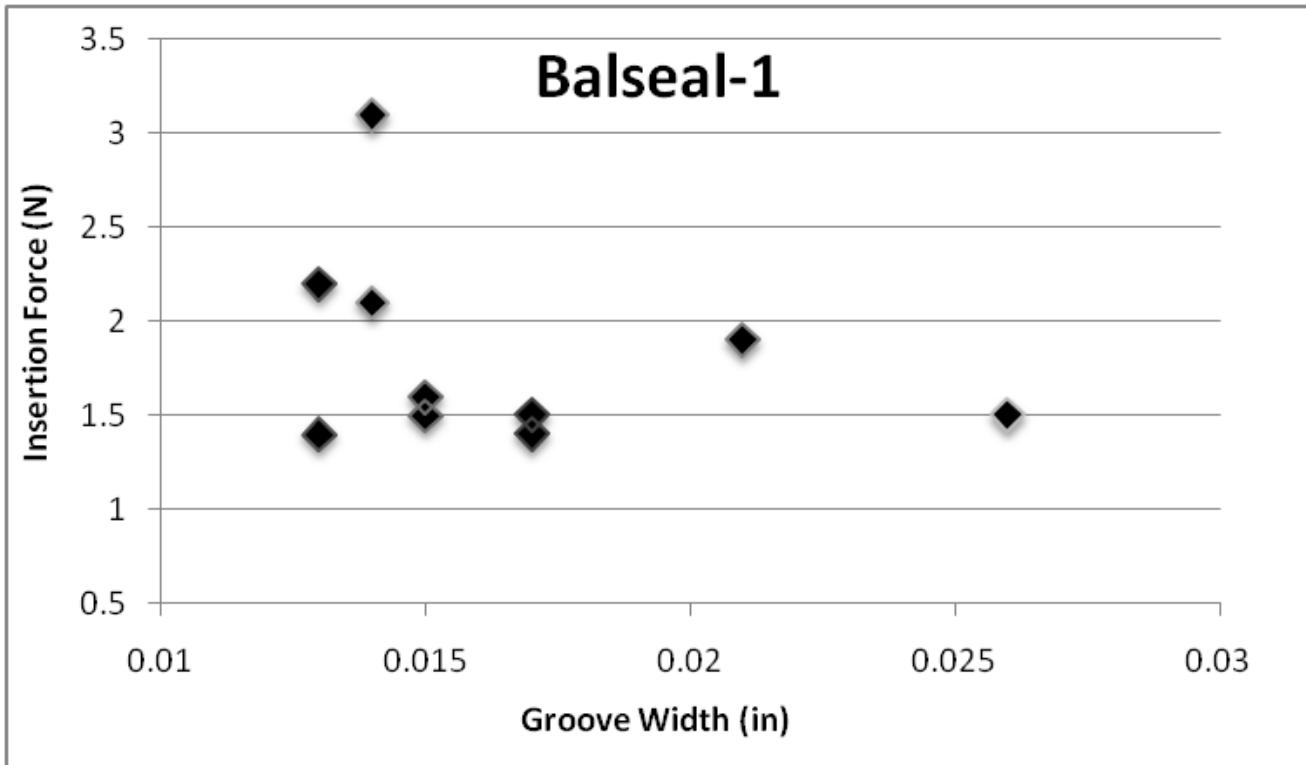


Figure 2-4 Effect of groove width on the insertion force for Balseal-1. Test order (Groove I to Groove VI).

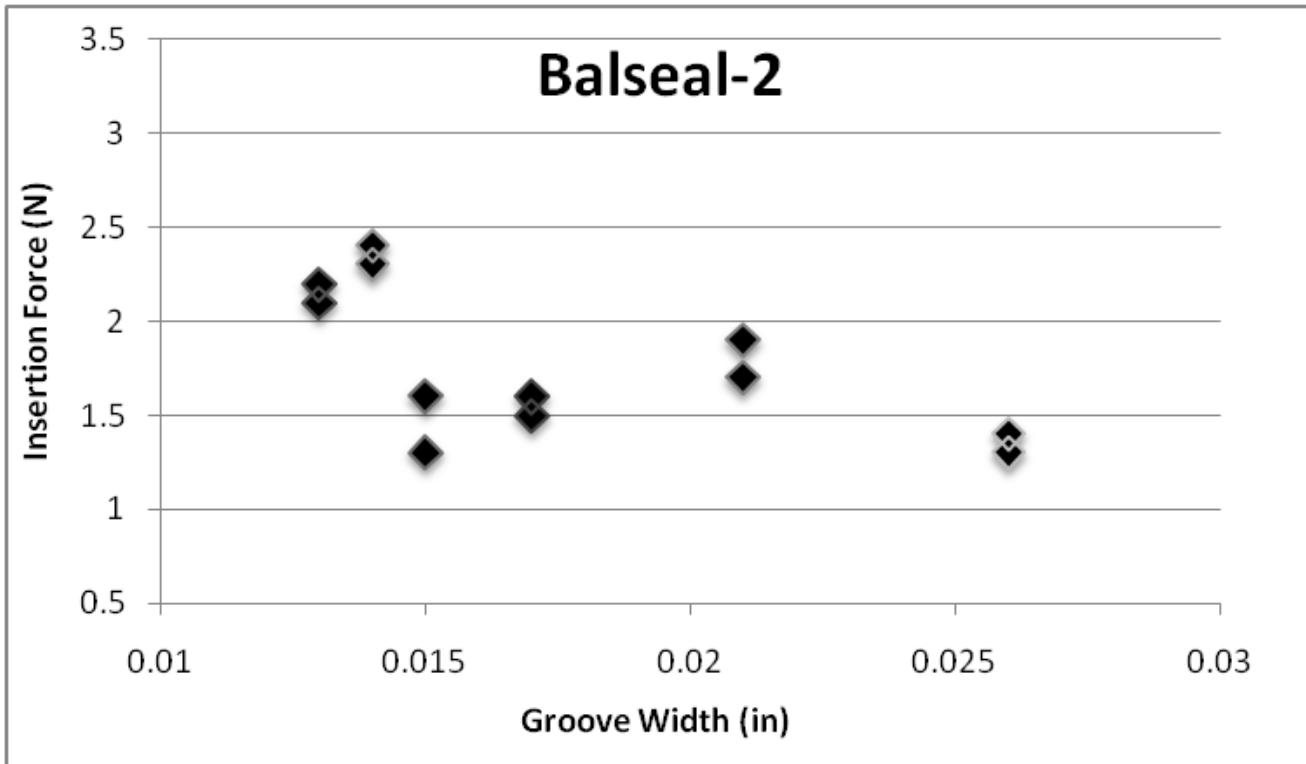
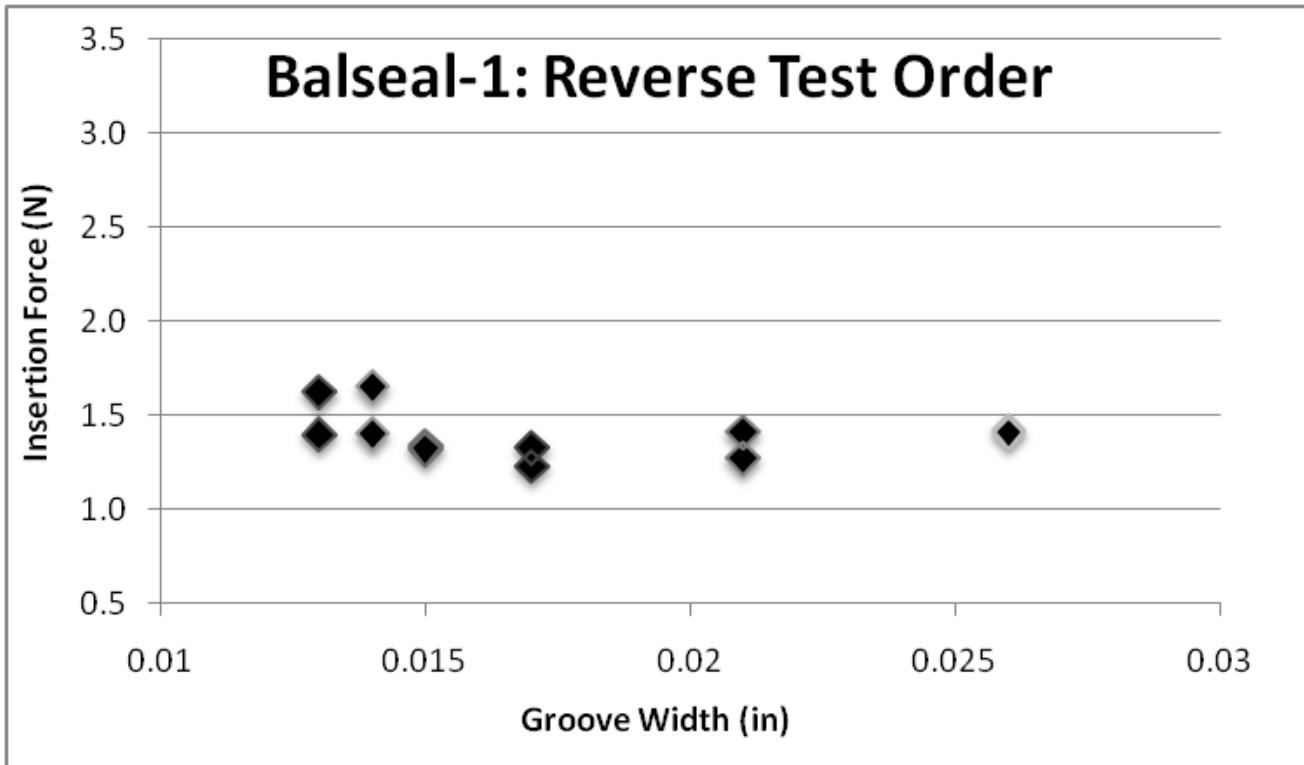


Figure 2-5 Effect of groove width on the insertion force for Balseal-2. Test order (Groove I to Groove VI).



**Figure 2-6 Effect of groove width on the insertion force for Balseal-1: Reverse test order
(Groove VI to Groove I).**

2.6. Conclusions

1. As the groove width doubled from 13mil to 26mil, insertion force varied between 2.5 N to 1.5 N.
2. Running force on 50mil ID was about 0.2 N.
3. The results from this study could have been compromised by: a). the experimental setup (BalSeal moving freely on the test pin), b). errors in force measurement because of the long test pin and c). relatively rough surface of the test pin.
4. Future study that uses a test set up and a test pin without the above shortcomings may give a better understanding of the effects of grove width.

3. Cyclic (Insertion/Extraction) Loading of BalSeal

3.1. Dates performed

June 2009

3.2. Objective

To study the effect of cyclic loading on BalSeal insertion and extraction forces.

3.3. Materials

- Two BalSeals, BalSeal-0 and BalSeal-1 were used in this study.
- The test pin received from Ardiem described in previous chapter was used in this study.

BalSeal #	Revision	Spring ID (mil)	No of coils	Notes
BalSeal-0	A/B	35	32	Spring ID measured before this study
BalSeal-1	A/B	34	31	Spring ID measured before this study

Table 3-1 BalSeals used in this study

3.4. Test Procedure

1. Attach a pin vise to the linear actuator and grip the test pin using a pin vise as in the previous study.
2. Grip the BalSeal using a big pin vise as shown in Figure 3-1.
3. Align the big pin vise with the test pin.
4. Position the big pin vise such that it is near groove-IV of the test pin as shown in Figure 3-1.
5. Start data acquisition (Sampling rate = 400Hz) to record load (using Interface 5lb load cell) and actuator displacement.
6. Subject the test pin to five cycles of sinusoidal displacement loading such that the BalSeal travels on the 50mil diameter of the test pin for few millimeters, falls in to the groove IV, climbs up, travels few millimeters on the 50mil diameter and returns back (Figure 3-2).
7. BalSeal-0 was subjected to 70 such loading cycles during which the BalSeal climbs up from groove IV 140 times. After the first 25 cycles the test pin was reversed and after 35 more cycles the BalSeal was also reversed.
8. BalSeal-1 was subjected to 10 such loading cycles over groove I followed by 10 loading cycles over groove VI.
9. Both BalSeals were examined in the ESEM (FEI Quanta 200 3D, FEI, Hillsboro, OR) after testing.

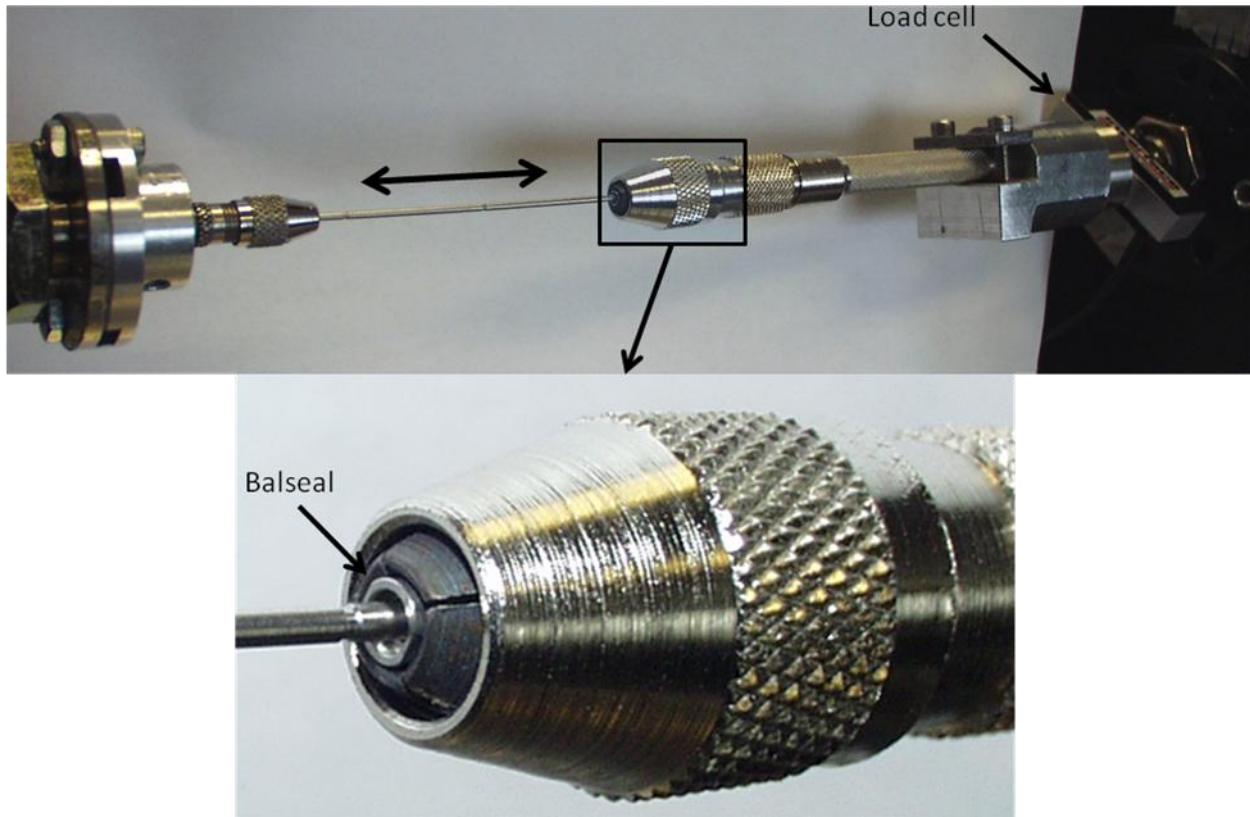


Figure 3-1 Test Setup

3.5. Results

1. A typical load-displacement curve for one complete loading cycle is shown in Figure 3-2.
2. Load-displacement curve for 4 consecutive cycles is shown in Figure 3-3 for BalSeal-0.
3. After 70 loading cycles, insertion/extraction force was about 1N for BalSeal-0 (Figure 3-4) and there was 2 mil increase in spring ID (Appendix 2).
4. Load evolution for 20 loading cycles is shown in Figure 3-5 for BalSeal-1. Note that the first 10 cycles were on groove I and the next 10 cycles were on groove VI.
5. Average insertion force for groove I and groove VI (Figure 3-5) were similar to the insertion forces measured in the previous study (Table 2-2) for BalSeal-1.
6. SEM images of the BalSeals before and after testing are shown in Appendix 2. BalSeal-0 exhibited significant spring wear after 70 cycles.

Cyclic Tests on Balseal : Insertion/Extraction forces

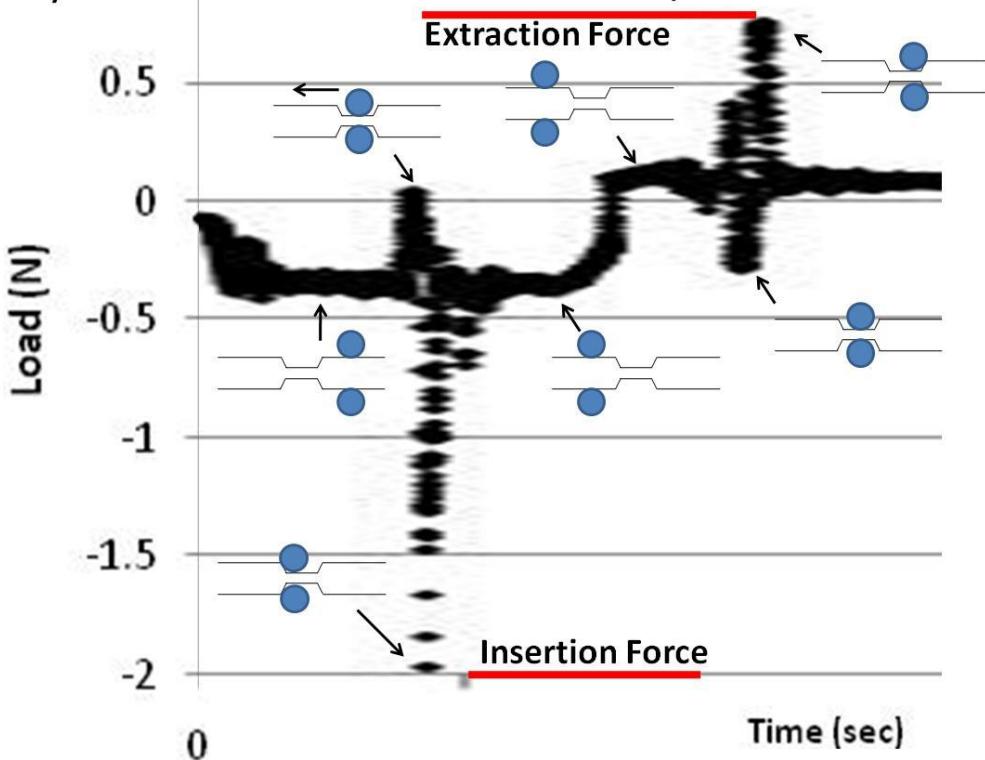


Figure 3-2 A typical load-displacement curve for one loading cycle

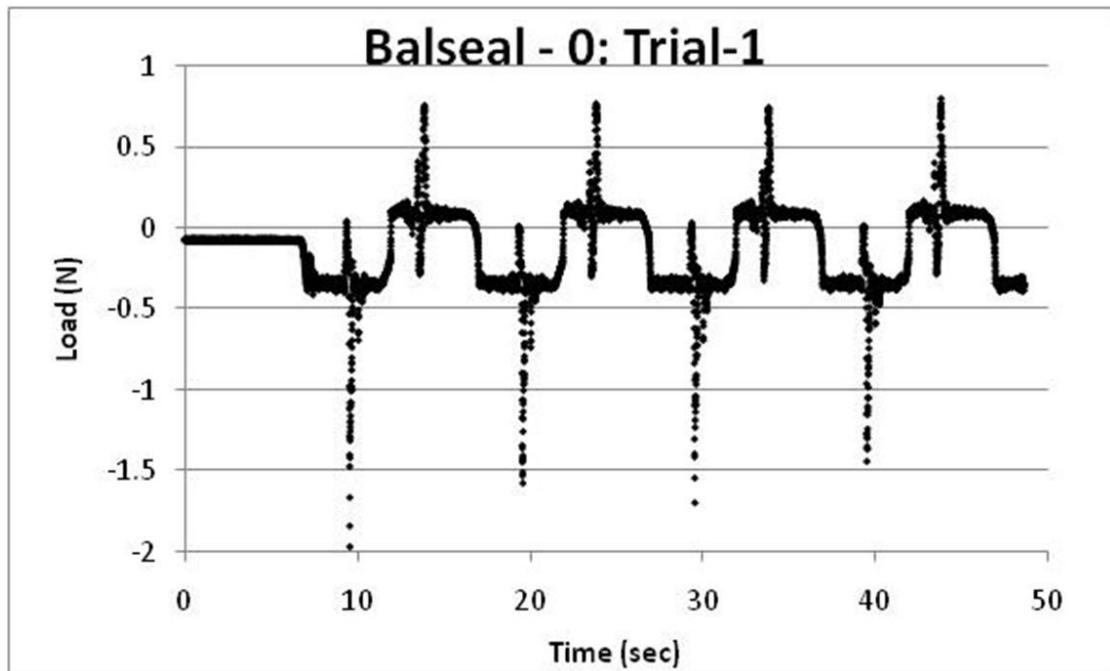


Figure 3-3 Load-displacement curve for four consecutive loading cycles

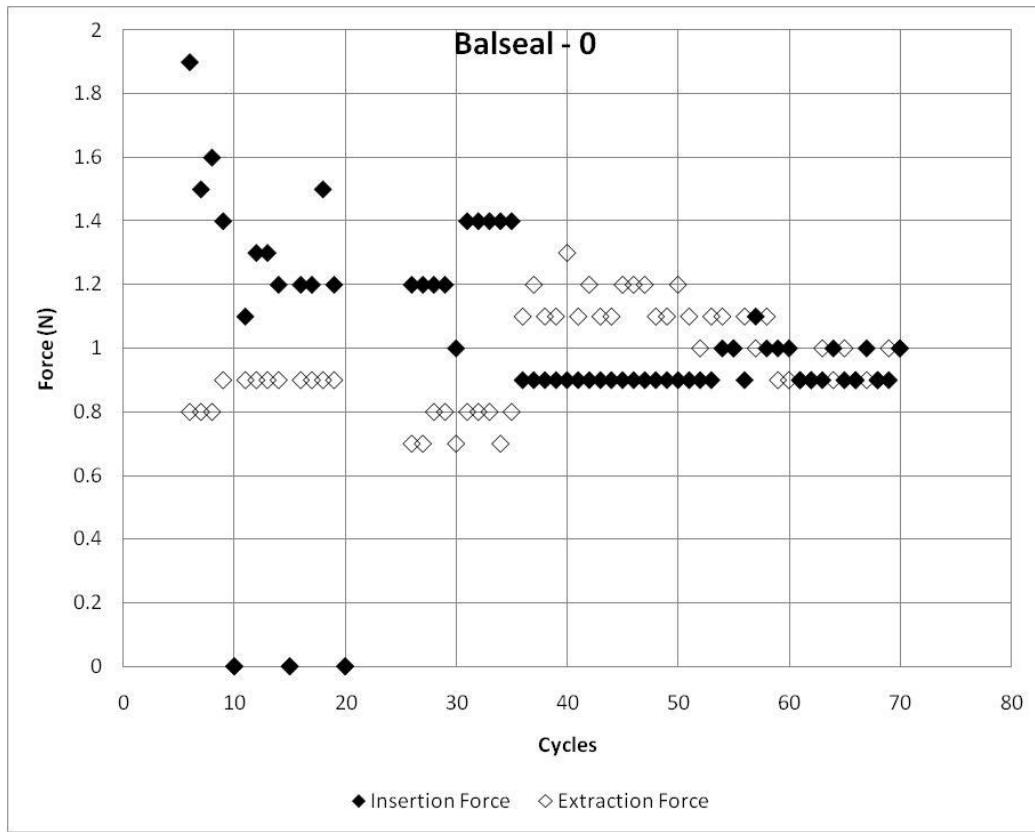


Figure 3-4 Force evolution with number of loading cycles for BalSeal-0

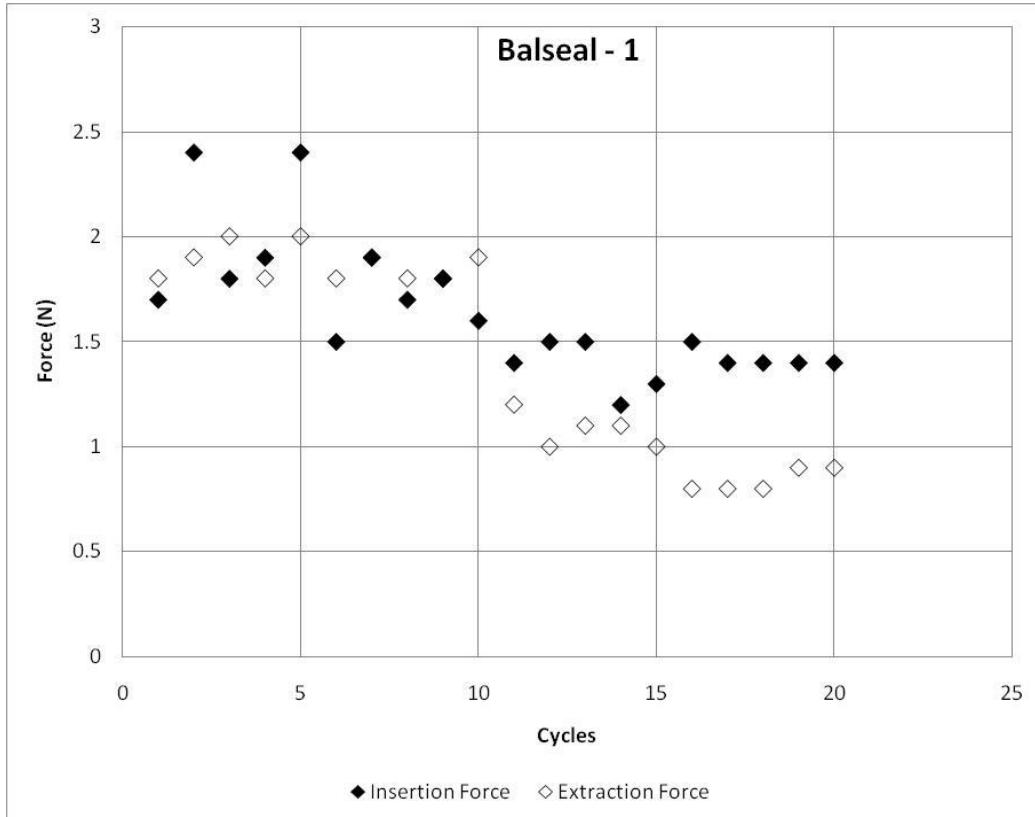


Figure 3-5 Force evolution with number of loading cycles for BalSeal-1. First 10 cycles were on groove I and the next 10 cycles were on groove VI.

3.6. Conclusions

1. After 140 insertions/extractions in this study, 7 insertions in the previous study and many random manual insertions, BalSeal-0 offered 1N extraction force in spite of significant wear of the spring.
2. There was no significant reduction in the forces after 40 insertions/extractions in this study and 40 insertions in the previous study for BalSeal-1.
3. More BalSeals need to be tested under cyclic loading to further understand the effects of multiple pin insertions on the BalSeal.

4. Effect of Chamfer Angle on BalSeal Insertion Force

4.1. Dates performed

July 2009 – August 2009

4.2. Objective

To study the effect of chamfer angle on BalSeal insertion force.

4.3. Materials

- Six BalSeals as listed in Table 4-1 were used in this study.
- Six gage pins of 50 mil diameter (Meyer gage company, South Winsor, CT) with one end chamfered to 20°, 30°, 40°, 45°, 50°, 60° angles were used in this study.
- Gage pins were chamfered and polished (to surface roughness of about 1µm) in FES center fabrication laboratory.

BalSeal #	Revision	Spring ID before testing (mil)	No of coils	Notes
BalSeal-4	A/B	36	33	Right Hand Twist coil
BalSeal-5	A/B	35	32	Right Hand Twist coil
BalSeal-6	A/B	35	35	Right Hand Twist coil
BalSeal-7	A/B	36	31	Right Hand Twist coil
BalSeal-8	A/B	35	33	Right Hand Twist coil
BalSeal-9	A/B	35	30	Left Hand Twist coil

Table 4-1 BalSeals used in this study

4.4. Test Procedure

1. Attach a pin vise to the linear actuator and grip the gage pin using a pin vise as in the previous studies.
2. Grip the BalSeal using a big pin vise as shown in Figure 3-1.
3. Align the big pin vise with the gage pin and position it in such a way that it is few mm away from the gage pin.
4. Start data acquisition (Sampling rate = 400Hz) to record load (using Interface 5lb load cell) and actuator displacement.
5. Move the actuator [Test speed = 0.85mm/sec (2in/min)] such that the gage pin inserts in to the BalSeal. Repeat the same procedure for two more times.
6. BalSeal-9 was subjected to 20 insertions using 60° pin.
7. All the BalSeals were examined in the ESEM (FEI Quanta 200 3D, FEI, Hillsboro, OR) before and after testing.

4.5. Results

1. SEM images of the chamfered gage pins are shown in Appendix 3.
2. As the chamfer angle increased from 20° to 60°, average insertion force increased from about 0.7 to 1.3N. Insertion force using 45° is smaller than that of 40° pin. This may be due to the fact that BalSeal-7 has less number of coils than BalSeal-6 (Table 4-2 & Figure 4-1). Trial-1 data is omitted in calculating the average force.
3. SEM images of the BalSeals before and after testing are shown in Appendix 3.
4. Insertion and Running forces remained constant for 20 insertions of 60° pin in BalSeal-9 (Figure 4-2) and BalSeal-6 (Figure 4-3).
5. No significant wear was observed even for BalSeal-9 in which 60° pin was inserted 20 times.
6. Insertion force using 60° pin Figure 4-3 was about 2.5 times more than that using 40° pin for BalSeal-6 (Table 4-2).
7. Insertion force using 60° pin for BalSeal-9 (30 coils) was about 40% less than that for BalSeal-6 (35 coils).

BalSeal #	No of coils	Chamfer Angle (deg)	BalSeal Spring ID (mil)		Insertion Force (N)			
			Before testing	After Testing	Trial-1	Trial-2	Trial-3	Ave
4	33	20	36	35	0.80	0.75	0.74	0.75
5	32	30	35	35	1.04	0.90	0.89	0.90
6	35	40	35	36	1.23	1.11	1.07	1.09
7	31	45	36	36	1.11	1.08	1.00	1.04
8	33	50	35	36	1.36	1.17	1.18	1.18
9	30	60	35	35	1.46	1.35	1.30	1.33

Table 4-2 Effect of chamfer angle on the Insertion forces

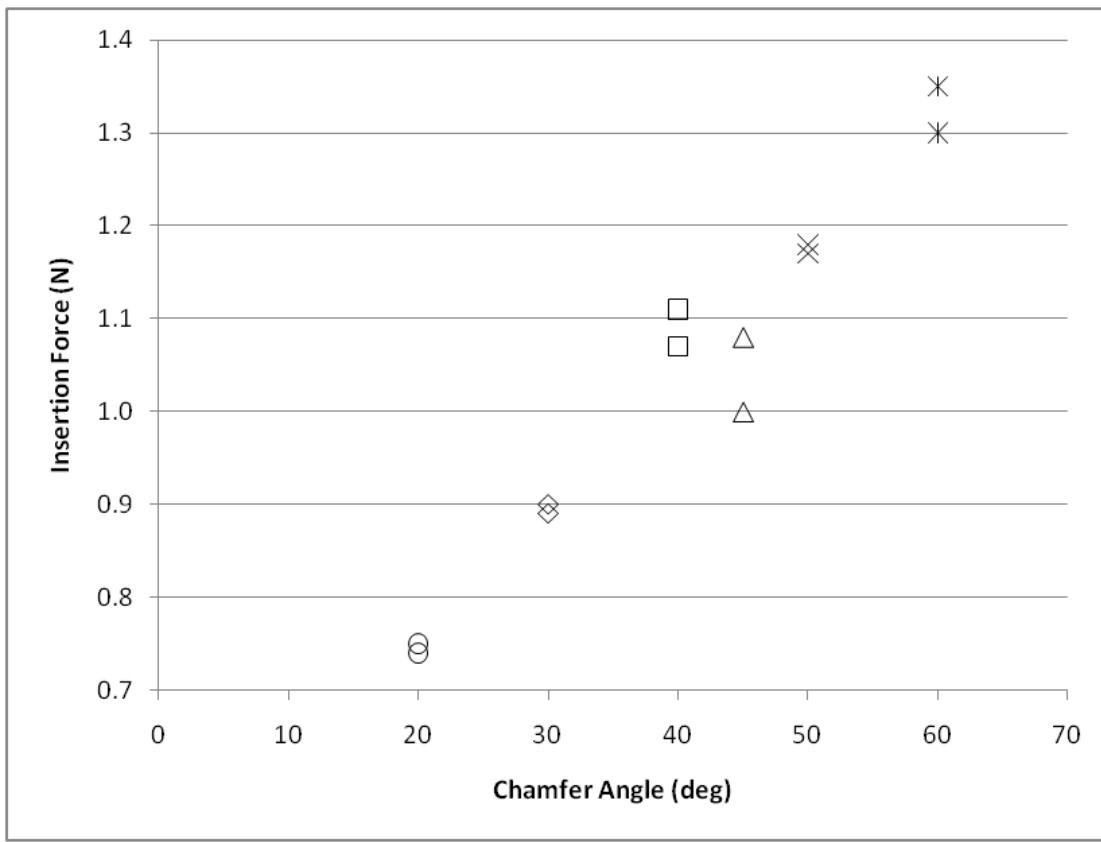
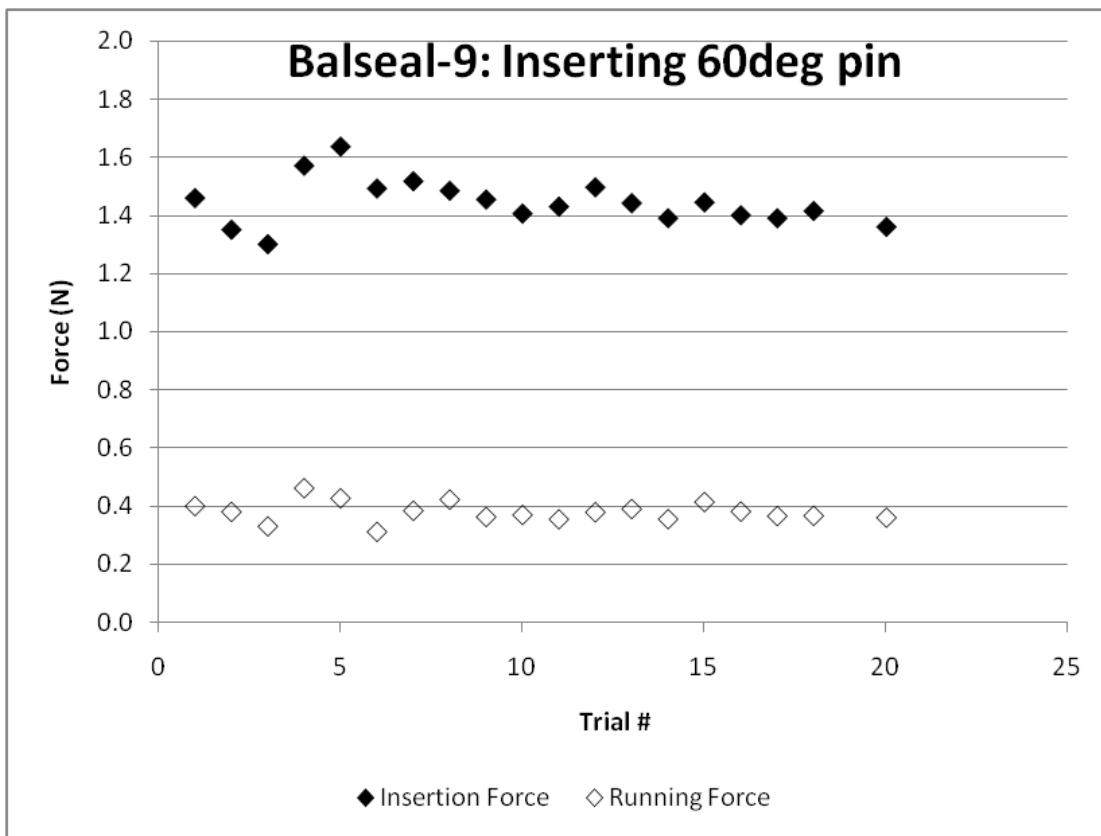


Figure 4-1 Effect of chamfer angle on the insertion force. (Trial-1 data is omitted)



**Figure 4-2 Force evolution for BalSeal-9 using 60° pin.
Running force data has a scatter of $\pm 0.025\text{N}$.**

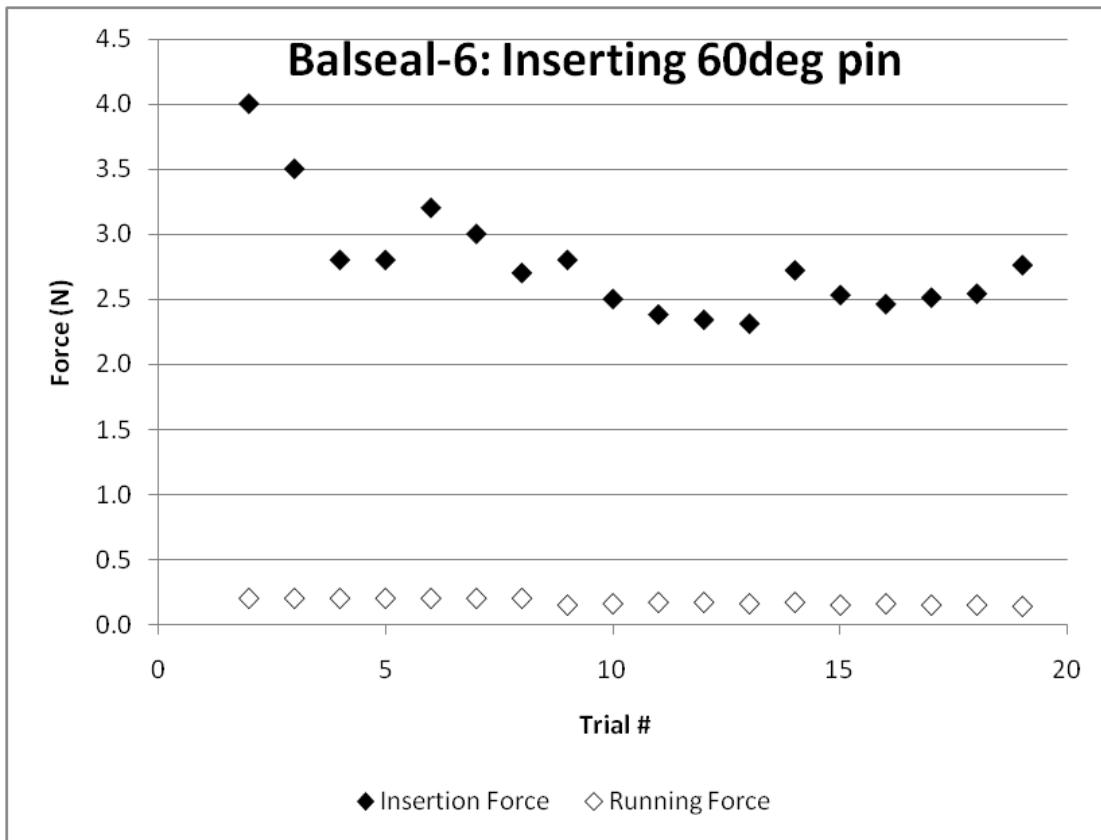


Figure 4-3 Force evolution for BalSeal-6 using 60° pin.
Running force data has a scatter of ±0.025N.

4.6. Conclusions

1. As the chamfer angle increased from 20° to 60°, insertion force increased from about 0.7 to 1.3N.
2. Insertion and Running forces remained constant for 20 insertions of 60° pin in BalSeal-9 (No significant wear) and BalSeal-6.
3. Insertion force using 60° pin for BalSeal-9 (30 coils) was about 40% less than that for BalSeal-6 (35 coils). Both BalSeal-9 and BalSeal-6 have identical spring ID of 35mil.

5. Effect of BalSeal Spring ID and Number of Coils on the Forces

5.1. Dates Performed

September 2009 – October 2009

5.2. Objective

To study the effect of BalSeal spring inner diameter and number of coils in the spring on BalSeal insertion and running forces.

5.3. Materials

- Fourteen BalSeals as listed were used in this study.
- Three gage pins of 50 mil diameter (Meyer gage company, South Winsor, CT) from the previous study with one end chamfered to 40°, 50°and 60° angles were used in this study.

BalSeal #	Revision	Spring ID before testing (mil)	No of coils
BalSeal-11	E	37	39
BalSeal-13	E	38	39
BalSeal-17	E	38	39
BalSeal-18	E	38	39
BalSeal-20	E	39	39
BalSeal-15	E	38	40
BalSeal-19	E	39	40
BalSeal-25	E	40	40
BalSeal-27	E	40	36
BalSeal-26	E	40	37
BalSeal-24	E	40	38
BalSeal-25	E	40	40
BalSeal-23	E	40	42
BalSeal-30	E	43	30

Table 5-1 BalSeals used in this study

5.4. Test Procedure

1. All the BalSeals were examined in the ESEM (FEI Quanta 200 3D, FEI, Hillsboro, OR) before testing.
2. Attach a pin vise to the linear actuator and grip the 40° gage pin using a pin vise as in the previous studies.
3. Grip the BalSeal using a big pin vise as shown in Figure 3-1.
4. Align the big pin vise with the gage pin and position it in such a way that it is few mm away from the gage pin.
5. Start data acquisition (Sampling rate = 400Hz) to record load (using Interface 5lb load cell) and actuator displacement.
6. Move the actuator [Test speed = 0.85mm/sec (2in/min)] such that the gage pin inserts in to the BalSeal. Repeat the same procedure for three more times.
7. Replace the 40° pin with a 50° pin and test four times as mentioned above. Then replace the 50° pin with 60° pin and test four more times. Thus each BalSeal is tested $3 \times 4 = 12$ times.
8. After these tests, running force on 40mil pin and 39mil pin were measured using some of the BalSeals mentioned in Table 5-1 and other BalSeals used in previous studies. Test matrix is provided in Appendix 4.

5.5. Results

1. The average (of trials 2, 3 &4) insertion force is plotted against spring ID in Figure 5-1. BalSeal-23 with 42 coils exhibited much higher force compared to the other BalSeals. BalSeal-30 with 30 coils exhibited much lower force compared to the other BalSeals.
2. BalSeals with number of coils = 30 to 42 alone is plotted in Figure 5-2. A clear decreasing trend of the insertion force with the increase in spring ID can be observed.
3. Larger the spring ID, less the effect of gage pin chamfer angle on the insertion force (Figure 5-2).
4. For BalSeals with 40mil ID, insertion force did not significantly change as the number of coils increased from 36 to 40 (Figure 5-3). However, insertion force did change for BalSeals with 38mil and 39mil ID (Figure 5-4 & Figure 5-5).
5. The effect of spring ID on the running force on 50mil pin was similar to that of the insertion force. Excluding the two outliers (BalSeal-23 and BalSeal-30), the running forces range from 0.2 to 0.4 N (Figure 5-6).
6. Running force on 40mil pin was about 0.025 to 0.25N for the BalSeals (ID = 35 to 39 mil, No of coils = 31 to 40) tested (Figure 5-7). The balseal with number of coils 39 is clear outlier for unknown reason.
7. Running force on 39mil pin was about 0.05 to 0.15N for the BalSeals (ID = 35 to 38 mil, No of coils = 31 to 39) tested (Figure 5-8). All the raw data is provided in Appendix 4.

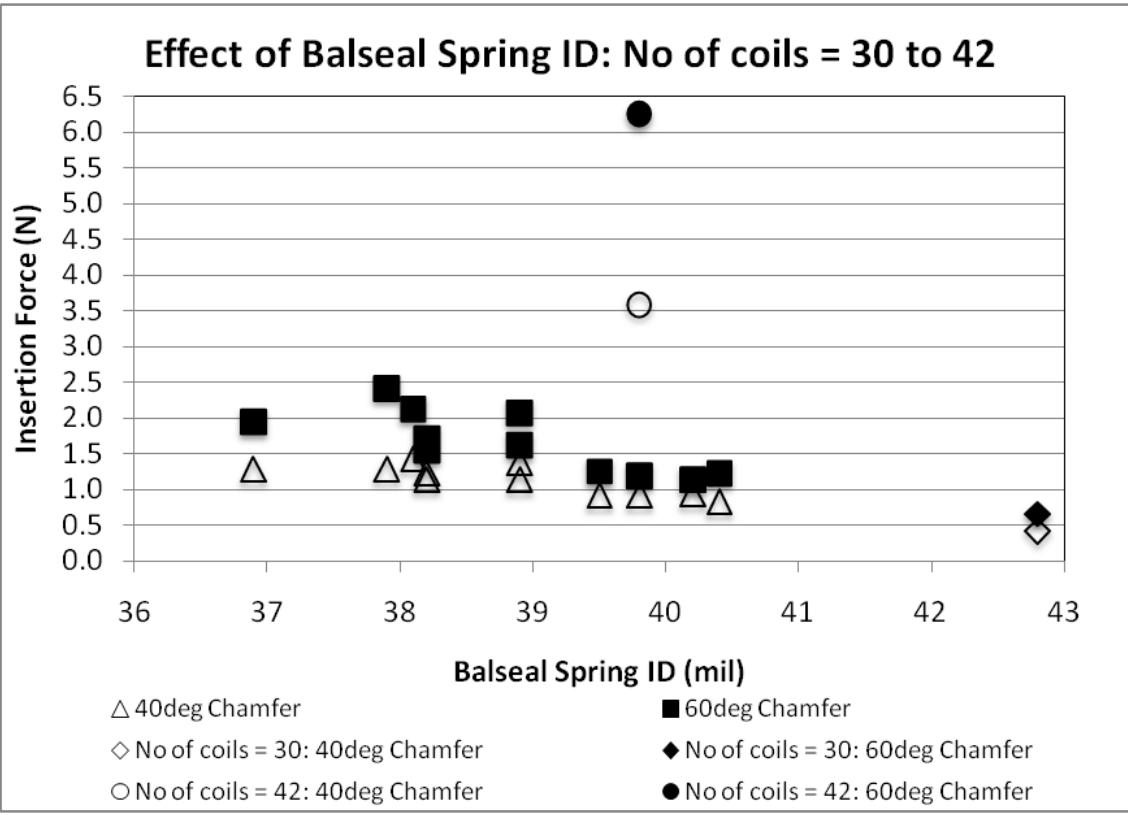


Figure 5-1 Effect of BalSeal spring ID on the average insertion force (No of coils = 30 to 42).
Standard deviation < 0.2N between trials.

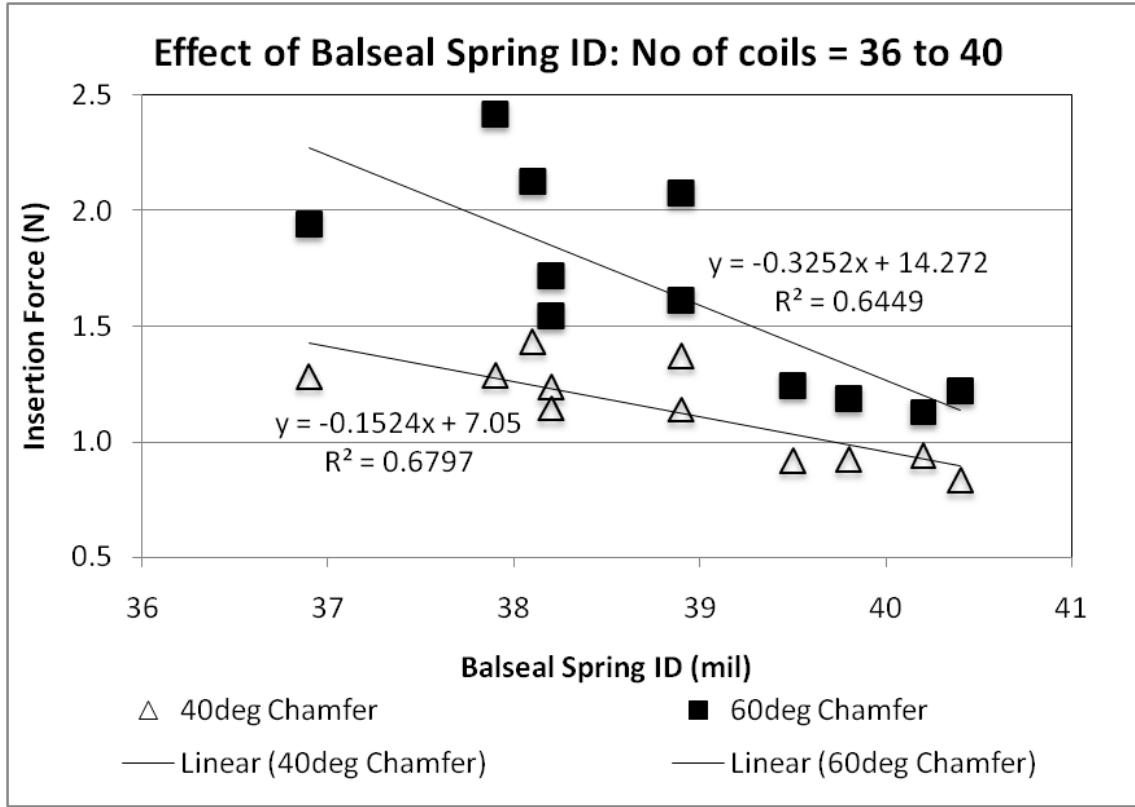


Figure 5-2 of BalSeal spring ID on the average insertion force (No of coils = 36 to 40).
Standard deviation < 0.2N between trials.

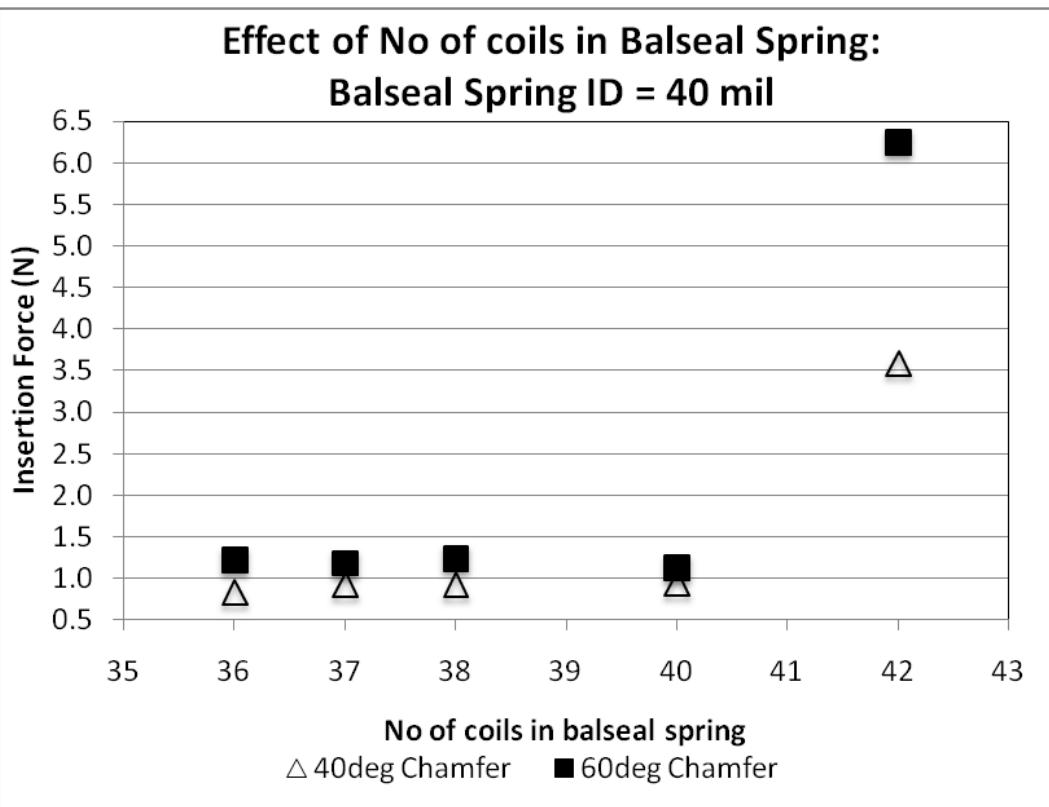


Figure 5-3 Effect of number of coils on the average insertion force (Spring ID = 40mil).
Standard deviation < 0.2N between trials.

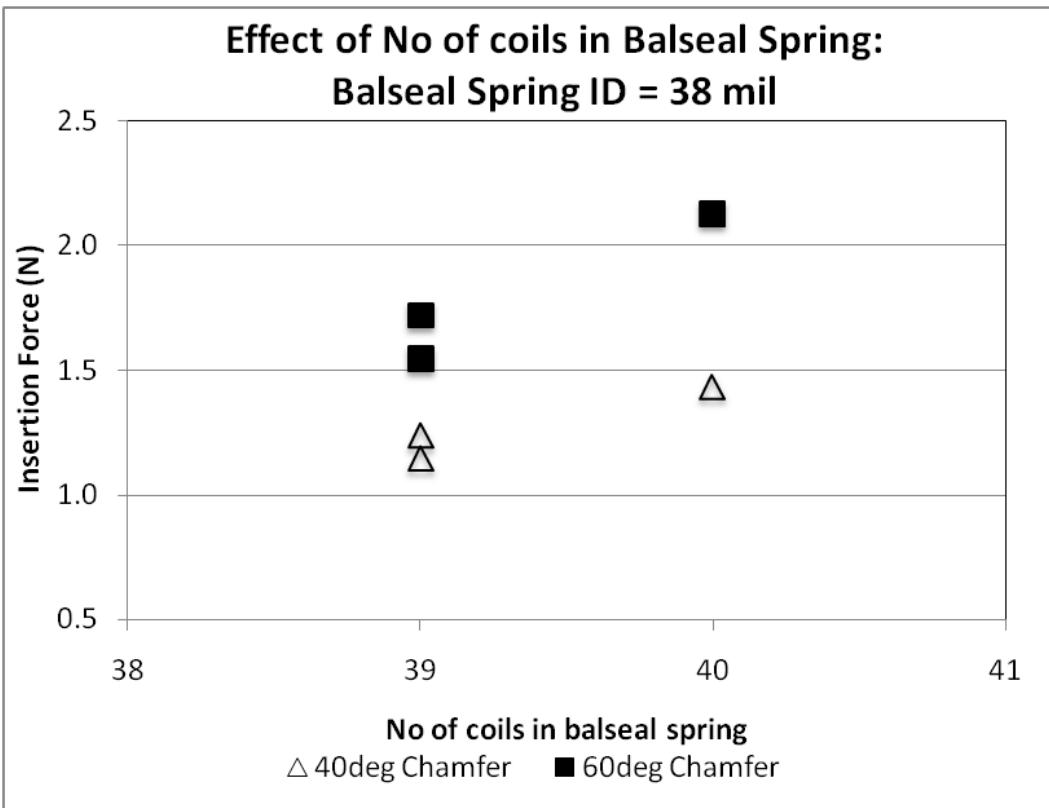


Figure 5-4 Effect of number of coils on the average insertion force (Spring ID = 38mil).
Standard deviation < 0.2 between trials.

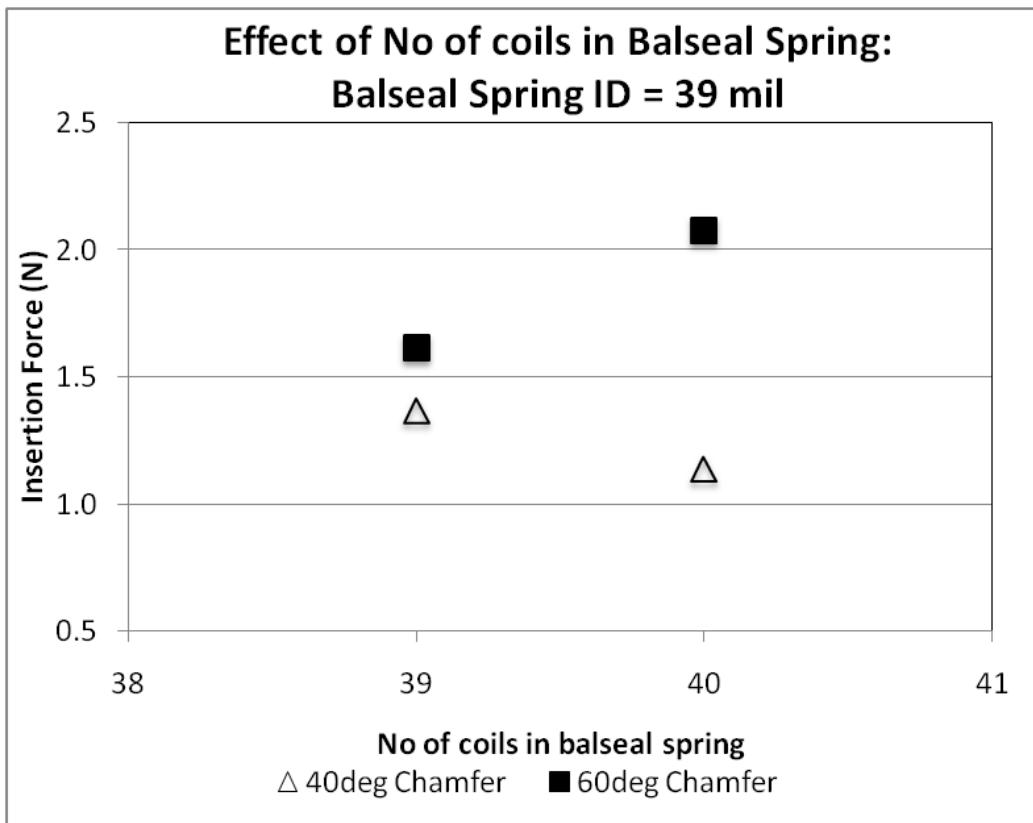


Figure 5-5 of number of coils on the average insertion force (Spring ID = 39mil).
Standard deviation < 0.2N between trials.

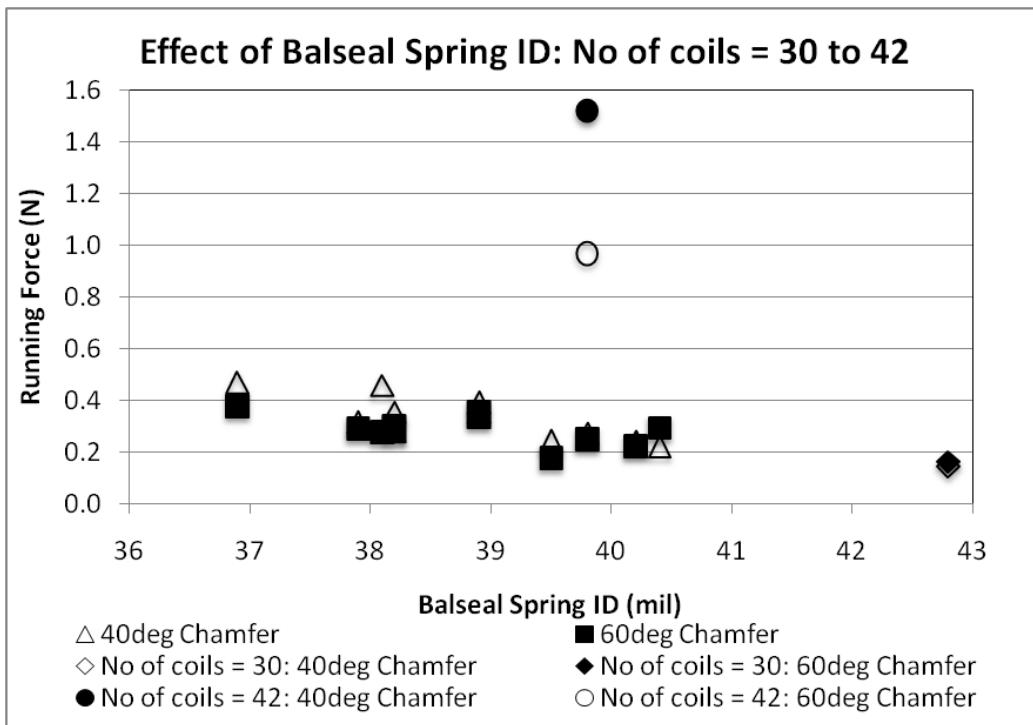


Figure 5-6 Effect of spring ID on the average running force on 50mil pin (No of coils = 30 to 42).
Running force data has a scatter of $\pm 0.025\text{N}$ and standard deviation < 0.01N between trials.

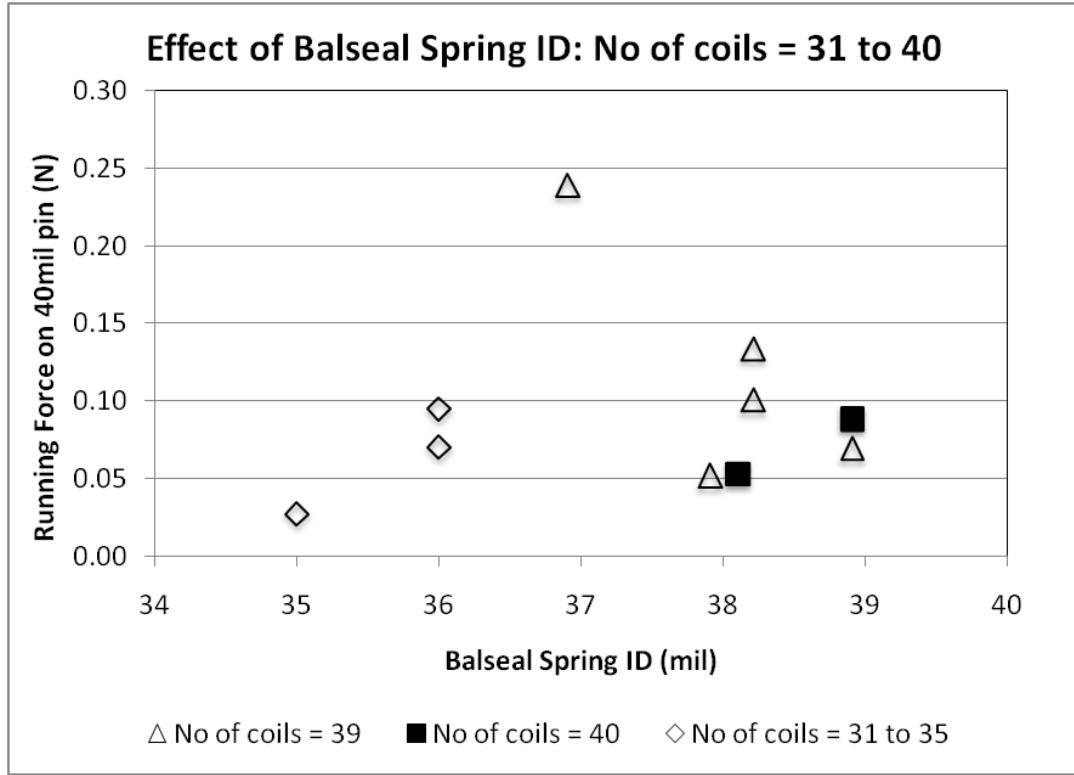


Figure 5-7 of spring ID on the average running force on 40mil pin (No of coils = 31 to 40). Running force data has a scatter of $\pm 0.025\text{N}$ and standard deviation $< 0.01\text{N}$ between trials.

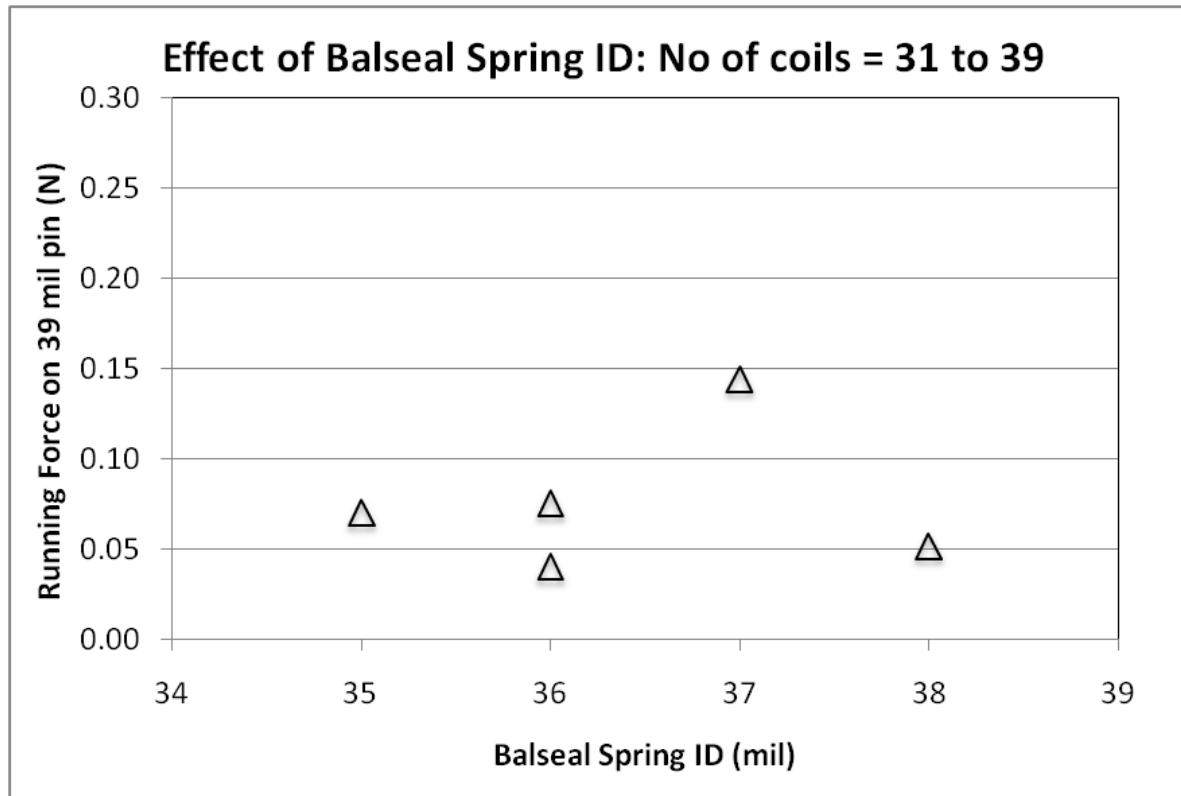


Figure 5-8 Effect of spring ID on the average running force on 39mil pin (No of coils = 31 to 39). Running force data has a scatter of $\pm 0.025\text{N}$ and standard deviation $< 0.01\text{N}$ between trials.

5.6. Conclusions

1. For the BalSeals with number of coils ranging from 30 to 42, a clear decreasing trend in the insertion and running force (on 50mil pin) with increase in spring ID was observed.
2. Insertion force using 50mil pin with 40° and 60° chamfer were within the range of 0.25 to 1.5N and 0.5 to 2.5N respectively for most of the BalSeals.
3. Larger the spring ID, less the effect of gage pin chamfer angle on the insertion force.
4. For most of the BalSeals, running force on 50mil, 40mil and 39mil pins were within the range of 0.2 to 0.4 N, 0.025 to 0.25N and 0.05 to 0.15N respectively.
5. Further testing with BalSeals of 38mil and 39mil spring ID and a range of number of coils would help to understand the effects of no of coils on the forces.

6. Summary & Observations

6.1. Effect of Groove Width on the Insertion Force

- As the groove width doubled from 13mil to 26mil, insertion force varied between 2.5 N to 1.5 N.
- The results from this study could have been compromised by: a). the experimental setup (BalSeal moving freely on the test pin), b). errors in force measurement because of the long test pin and c). relatively rough surface of the test pin.

6.2. Effect of Cyclic (Insertion/Extraction) Loading

- After more than 150 insertions/extractions by 50mil pin, BalSeal-0 offered 1N extraction force in spite of significant wear of the spring.
- After 80 insertions/extractions by 50mil pin, no significant reduction in the forces was observed for BalSeal-1.

6.3. Effect of Pin Chamfer Angle on the Insertion Force

- As the chamfer angle increased from 20° to 60°, insertion force increased from about 0.7 to 1.3N.
- Insertion and Running forces remained constant for 20 insertions of 60° pin in BalSeal-9 (No significant wear) and BalSeal-6.
- Insertion force using 60° pin for BalSeal-9 (30 coils) was about 40% less than that for BalSeal-6 (35 coils). Both BalSeal-9 and BalSeal-6 have identical spring ID of 35mil.

6.4. Effect of Balseal Spring Id and No of Coils on Insertion and Running Force

- For the BalSeals with number of coils ranging from 30 to 42 a clear decreasing trend in the insertion and running force (on 50mil pin) with increase in spring ID was observed.
- Insertion force using 50mil pin with 40° and 60° chamfer were within the range of 0.25 to 1.5N and 0.5 to 2.5N respectively for most of the BalSeals.
- For most of the BalSeals, running force on 50mil, 40mil and 39mil pins were within the range of 0.2 to 0.4 N, 0.025 to 0.25N and 0.05 to 0.15N respectively.

7. Questions, Discrepancies, Unresolved Issues, Further Testing

7.1. Unresolved Issues

7.1.1. Testing Issues

- Maintaining alignment of pin and BalSeal during testing so that the load cell does not see any lateral forces

7.1.2. Other Issues

- Quantifying BalSeal spring wear
- Effect of spring wear on the contact electrical properties
- Effect of lubrication (saline water/body fluid) on the BalSeal insertion and Running forces

7.2. Further Testing

- The results from the study presented in Chapter 2 could have been compromised by: a). the experimental setup (BalSeal moving freely on the test pin), b). errors in force measurement because of the long test pin and c). relatively rough surface of the test pin. Future study that uses a test set up and a test pin without the above shortcomings may give a better understanding of the effects of grove width.
- More BalSeals need to be tested under cyclic loading to further understand the effects of multiple pin insertions on the BalSeal.
- Force testing of BalSeals with 38mil and 39mil spring ID and a range of number of coils is required to understand the effects of number of coils on the forces.

8. BalSeal Inventory (as of 27 Oct 2009)

BalSeal ID	Revision	Spring ID (mil)		No of coils	Comments
		Ardiem	CWRU		
0	Rev-A/B	NA	35	32	tested many number of times
1	Rev-A/B	NA	34	31	on all 6 grooves in the Test rod 6 times, on groove I and VI 25 times
2	Rev-A/B	NA	35	33	on all 6 grooves in the Test rod 3 times, over a smooth 50mil pin 8 times
3	Rev-A/B	NA	36	31	Not tested yet, Spring Coil LH Twist
4	Rev-A/B	NA	36	33	on 20deg chamfer 50 mil pin 3 times, over a smooth 50mil pin 2 times, On 39 and 40mil pin thrice
5	Rev-A/B	NA	35	32	on 30deg chamfer 50 mil pin 3 times
6	Rev-A/B	NA	35	35	on 40deg chamfer 50 mil pin 3 times, on 60deg chamfer 50 mil pin once, On 39 and 40 mil pin thrice
7	Rev-A/B	NA	36	31	on 45deg chamfer 50 mil pin 3 times, On 39mil pin thrice, On 40mil pin four times
8	Rev-A/B	NA	35	33	on 50deg chamfer 50 mil pin 3 times
9	Rev-A/B	NA	35	30	on 60deg chamfer 50 mil pin 20 times, Spring Coil LH Twist
10	Rev-A/B	NA	35	32	Not tested yet
11	Rev-E	37	37	39	on 20, 40, 60 deg 50mil pin 4 times each, On 40mil pin four times
12	Rev-E	37	37	39	On 39mil pin thrice
13	Rev-E	37	38	39	on 20, 40, 60 deg 50mil pin 4 times each, On 40mil pin four times
14	Rev-E	37	37	38	Not tested yet
15	Rev-E	38	38	40	on 20, 40, 60 deg 50mil pin 4 times each, On 40mil pin four times
16	Rev-E	38	38	40	Not tested yet
17	Rev-E	38	38	39	on 20, 40, 60 deg 50mil pin 4 times each, On 39mil pin thrice, On 40mil pin four times
18	Rev-E	38	38	39	on 20, 40, 60 deg 50mil pin 4 times each, On 40mil pin four times
19	Rev-E	39	39	40	on 20, 40, 60 deg 50mil pin 4 times each, On 40mil pin four times
20	Rev-E	39	39	39	on 20, 40, 60 deg 50mil pin 4 times each, On 40mil pin four times
21	Rev-E	39	39	41	Not tested yet
22	Rev-E	39	39	39	Not tested yet
23	Rev-E	40	40	42	on 20, 40, 60 deg 50mil pin 4 times each
24	Rev-E	40	40	38	on 20, 40, 60 deg 50mil pin 4 times each
25	Rev-E	40	40	40	on 20, 40, 60 deg 50mil pin 4 times each
26	Rev-E	40	40	37	on 20, 40, 60 deg 50mil pin 4 times each
27	Rev-E	41	40	36	on 20, 40, 60 deg 50mil pin 4 times each
28	Rev-E	NA	40	37	Not tested yet
29	Rev-E	41	41	36	Not tested yet
30	Rev-E	43	43	30	on 20, 40, 60 deg 50mil pin 4 times each

9. Testing at BalSeal Engineering Inc.

Balseal Test Report from Ardiem Medical and Balseal Engg

Ref: PRJ-NNPS-CONS-REP-34 Ardiem Report on BalSeals 4-Nov-08

PRJ-NNPS-CONS-DWG-90 Ardiem BalSeal Test Pin 15-May-09

PRJ-NNPS-CONS-REP-34 Ardiem Report on BalSeals 18-Nov-08

Balseal spring

- Material: 80% Platinum, 20% Iridium (Verified using Emission spectroscopy)
- Wire diameter: 0.003"
- Tensile strength: 160 – 200 KSI
- Elongation at break: 0.7 – 5%

Note:

- ID gage diameter : 0.05"
- ID gage material: Stainless steel
- Test method: D
- **ID gage chamfer angle ???**
- **Test speed ???**

Balseal housing

- Material: 316L ESR VM
- Diameter: 0.125"
- Tensile strength: 93 KSI

Balseal Rev A

Qty: 54

Spring ID: 0.035" to 0.037"

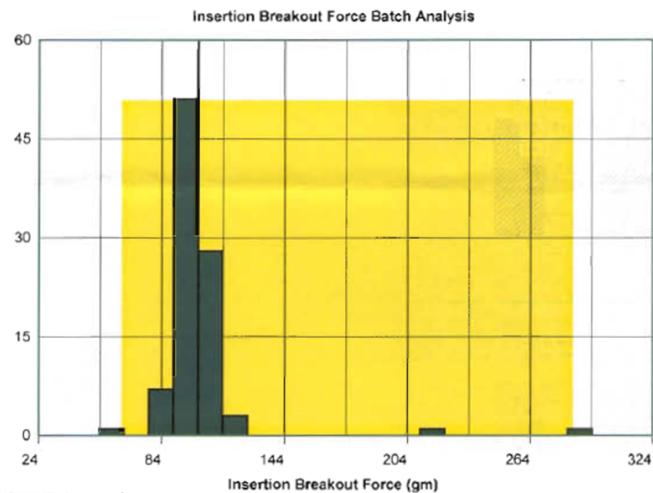
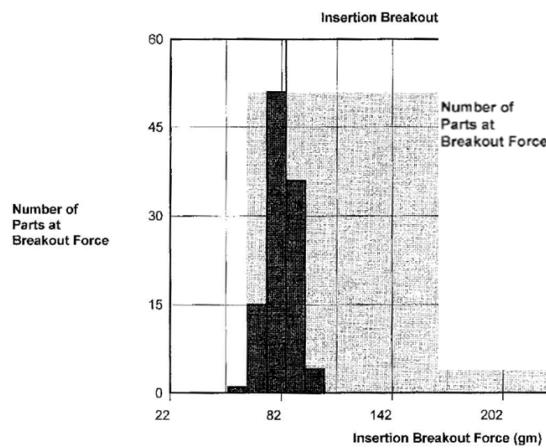
(based on measurements from 8 Balseals)

Balseal Rev A

Qty: 46

Spring ID: 0.033" to 0.036"

(based on measurements from 45 Balseals) *



Force	Min (N)	Max (N)	Ave (N)	STD (N)
Breakout	0.62	2.80	0.82	0.21
Running	0.20	1.74	0.24	-

Force	Min (N)	Max (N)	Ave (N)	STD (N)
Breakout	0.64	2.85	1.02	0.24
Running	0.01	1.56	0.29	0.16

* One Balseal measured 0.039"

Force readings are divided into two regions: the breakout force region and the running force region. The breakout force region is defined as the first 20% of gage travel. The running force region is defined as the last 80% of gage travel. These parameters have provided reliable and consistent seal force results.

Source: http://www.BalSeal.com/files/tech_library/tr54_020707132219.pdf

Balseal Test Report from Ardiem Medical and Balseal Engg

Ref: Balseal_COC_090722.pdf

Balseal housing

- Material: 316L ESR VM
- Diameter: 0.125"
- Tensile strength: 71 KSI min / 27.5 KSI min Yield (Annealed)

Note:

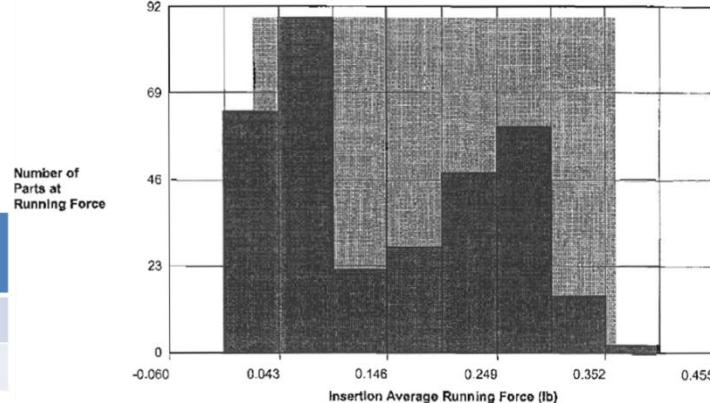
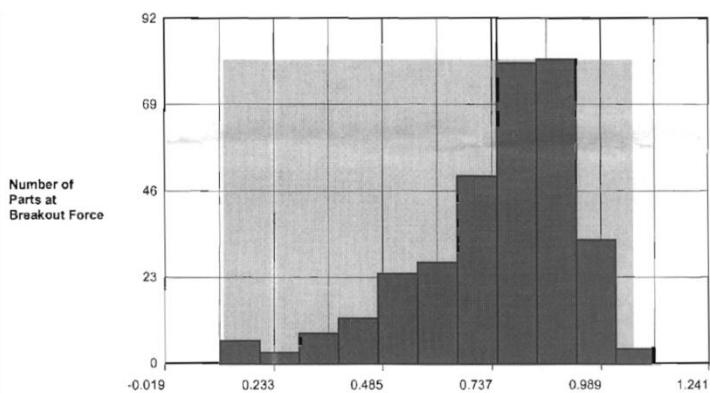
- ID gage diameter : 0.05"
- ID gage material: Stainless steel

-Test Method: T

Balseal Rev E : Qty: 250

No-Go Pin Size	QTY.
0.037	20
0.038	140
0.039	77
0.040	10
0.041	2
0.043	1
Total =	250

Force	Min (N)	Max (N)	Ave (N)	STD (N)
Breakout	0.5	4.7	3.3	0.8
Running	0.08	1.6	0.6	0.5



Note: Units on the above two plots needs to be double checked with BalSeal Engineering.

10. Appendices

Appendix -1 (Appendix-1.pptx)

- BalSeal Test pin drawing [Ardiem Medical Inc] (Slide 2)
- Groove-I and Groove-II magnified optical microscope image (Slides 3-4)
- SEM images of BalSeal – 0 after testing (Slides 5-14)
- BalSeal - 1before testing (Slides 15-18)
- BalSeal - 1before testing (Slides 19-22)
- SEM images of BalSeal – 2 after testing (Slides 23-26)

Appendix – 2 (Appendix-2.pptx)

- BalSeal – 0 after cyclic testing (Slides 2-10)

Appendix – 3 (Appendix-3.pptx)

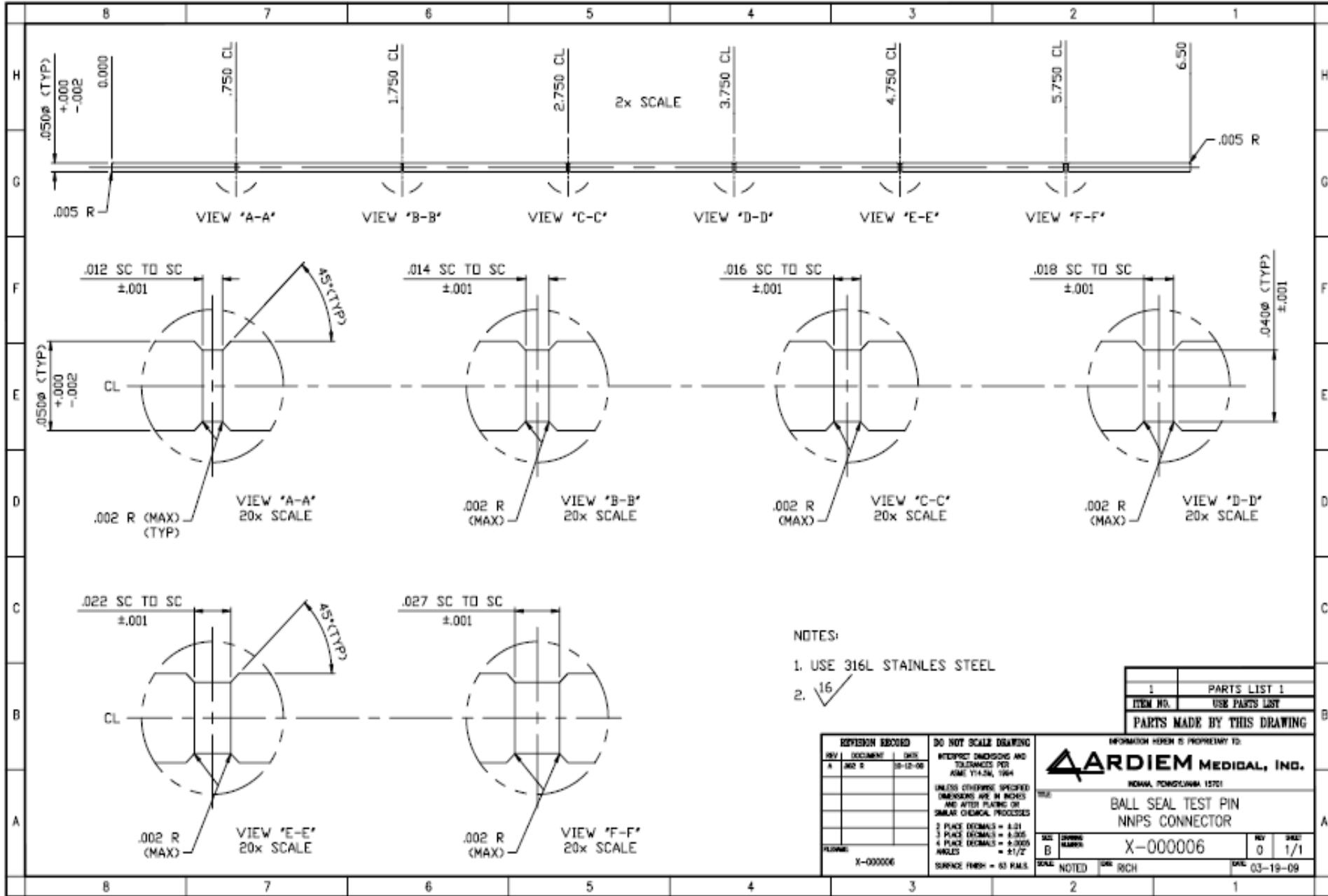
- SEM images of BalSeal – 4, BalSeal – 5, BalSeal – 6, BalSeal – 7, BalSeal – 8, BalSeal – 9 before and after testing (Slides 2-16)
- SEM images of BalSeal-9 after 20 cycles (Slides 17-18)

Appendix – 4 (Appendix-4.pptx)

- Test Matrix for running force tests on 39mil and 40mil pin (Slide 2)



Appendix 1

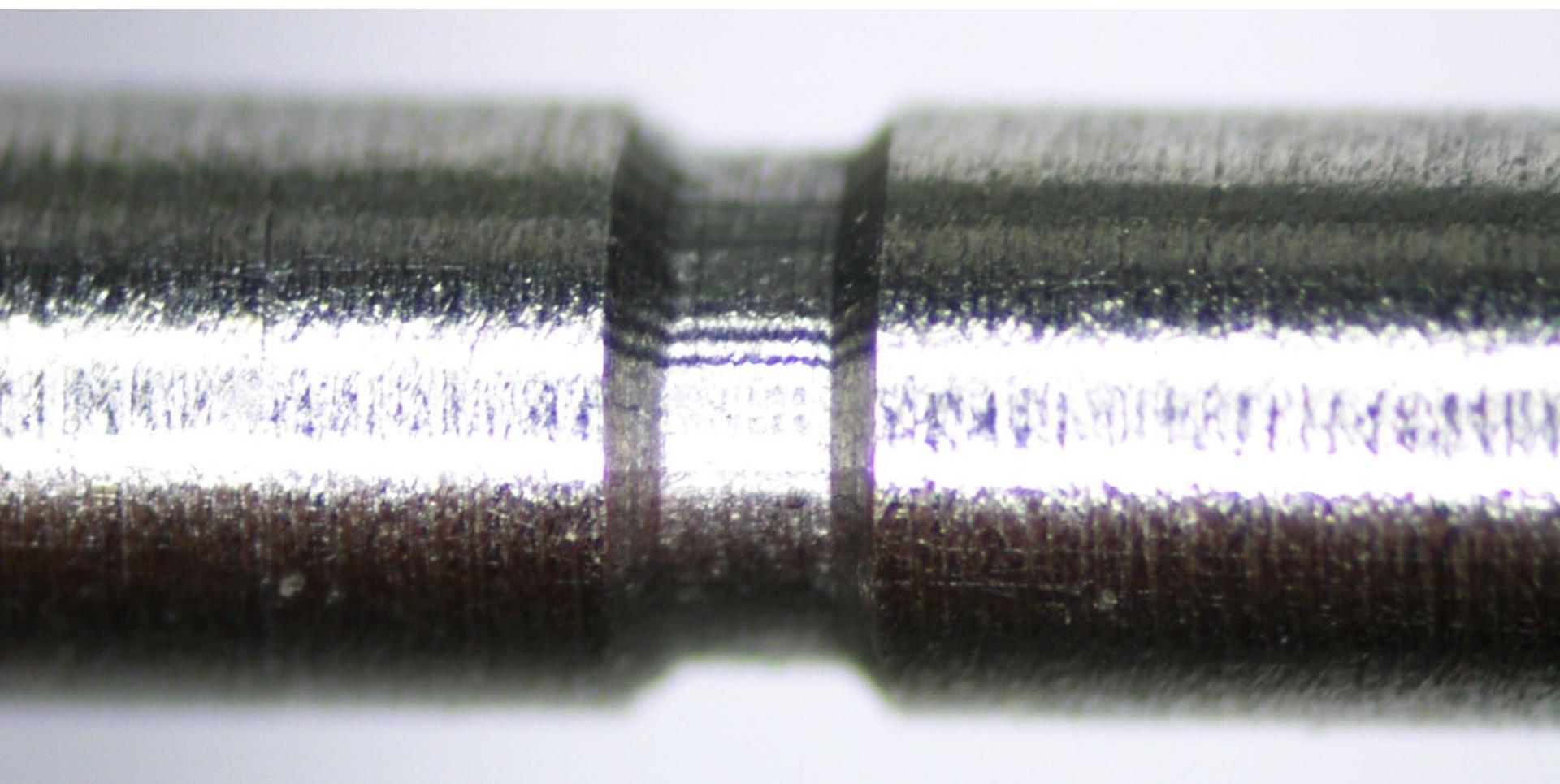


NOTES:

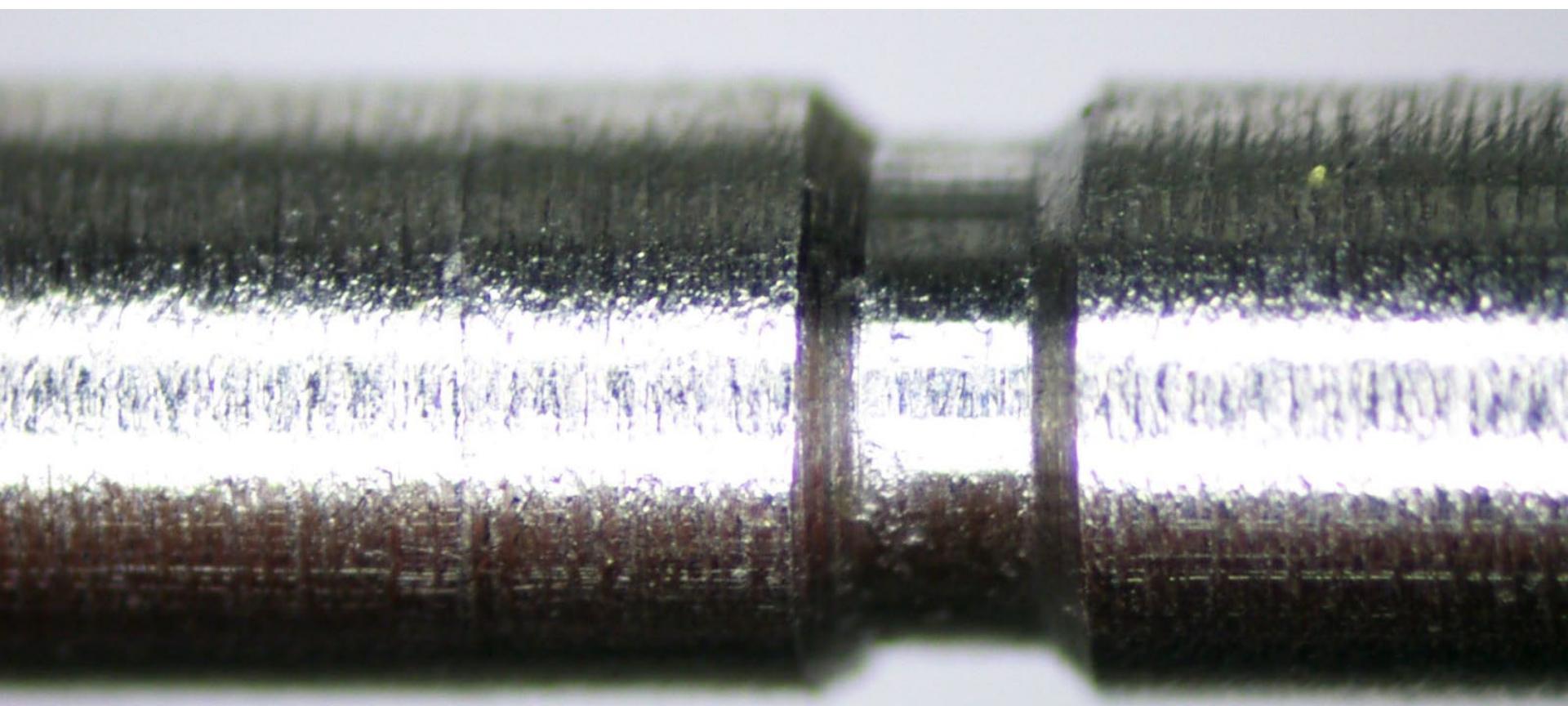
1. USE 316L STAINLESS STEEL
 2. ✓¹⁶

REVISION RECORD			DO NOT SCALE DRAWING		INFORMATION HEREIN IS PROPRIETARY TO:			
REV	DOCUMENT	DATE	INTERPRET DIMENSIONS AND TOLERANCES PER ASME Y14.5M, 1984		 ARDIEM MEDICAL, INC.			
A	302 R	08-12-00	UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES AND AFTER PLATING OR SIMILAR CHEMICAL PROCESSES		IAWA, PENNSYLVANIA 15701			
			2 PLATE DIMENSIONS = ±.01 3 PLATE DIMENSIONS = ±.005 4 PLATE DIMENSIONS = ±.005 ANGLES = ±1/2°		BALL SEAL TEST PIN NNPS CONNECTOR			
DRAWING NUMBER: X-000006			REV	DATE				
			B	X-000006		0	1/1	
SPECIAL NOTES			NOTED	RICH	DATE 03-19-09			
SURFACE FINISH = 65 RAUS.								

Groove – I



Groove – II



BALSEAL-0

After manually
engaging/disengaging
on the Testpin for
many times and after
force testing

ID = 0.89mm = 0.035"



HV
20.00 kV

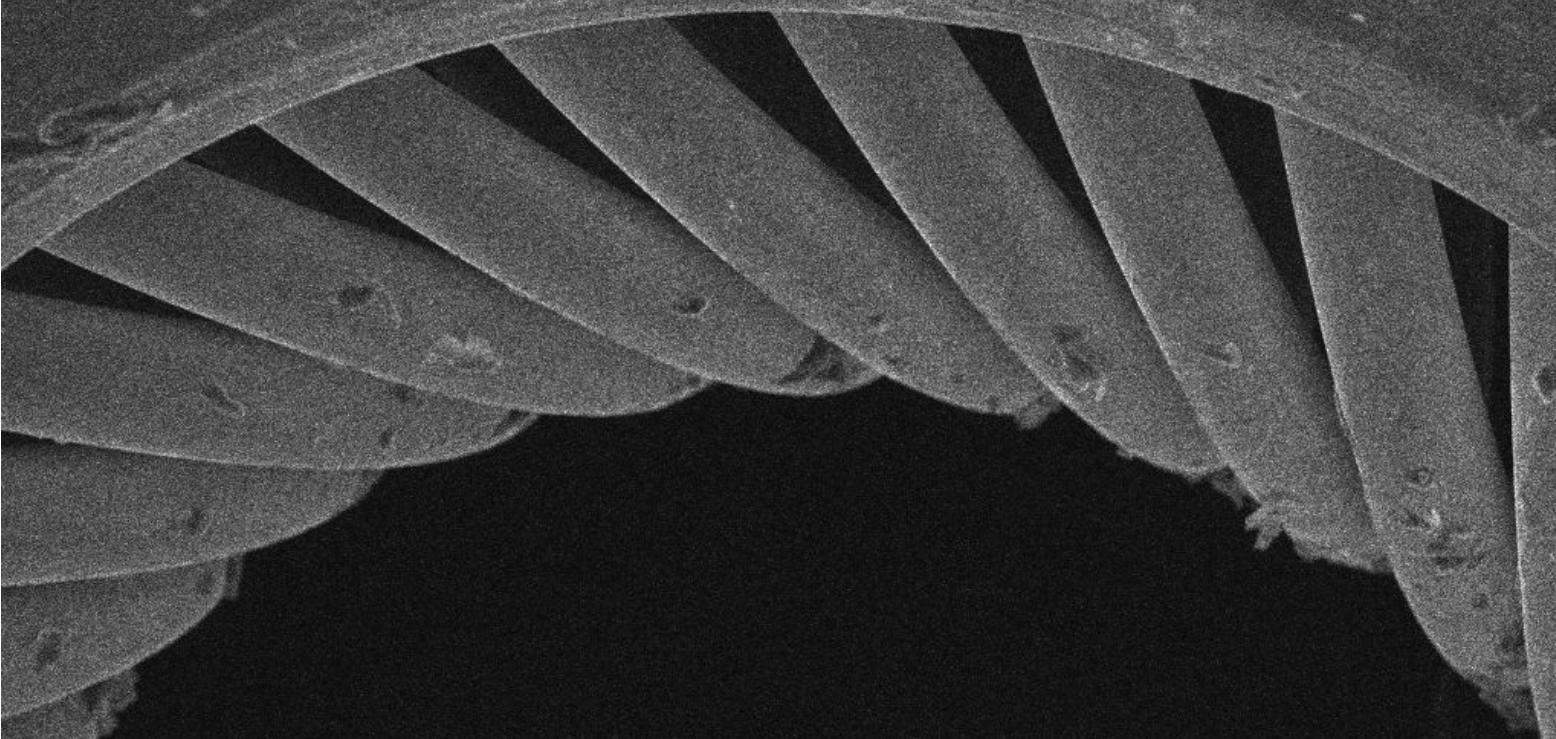
mag 田
75 x

5/15/2009
12:27:33 PM

WD
12.1 mm

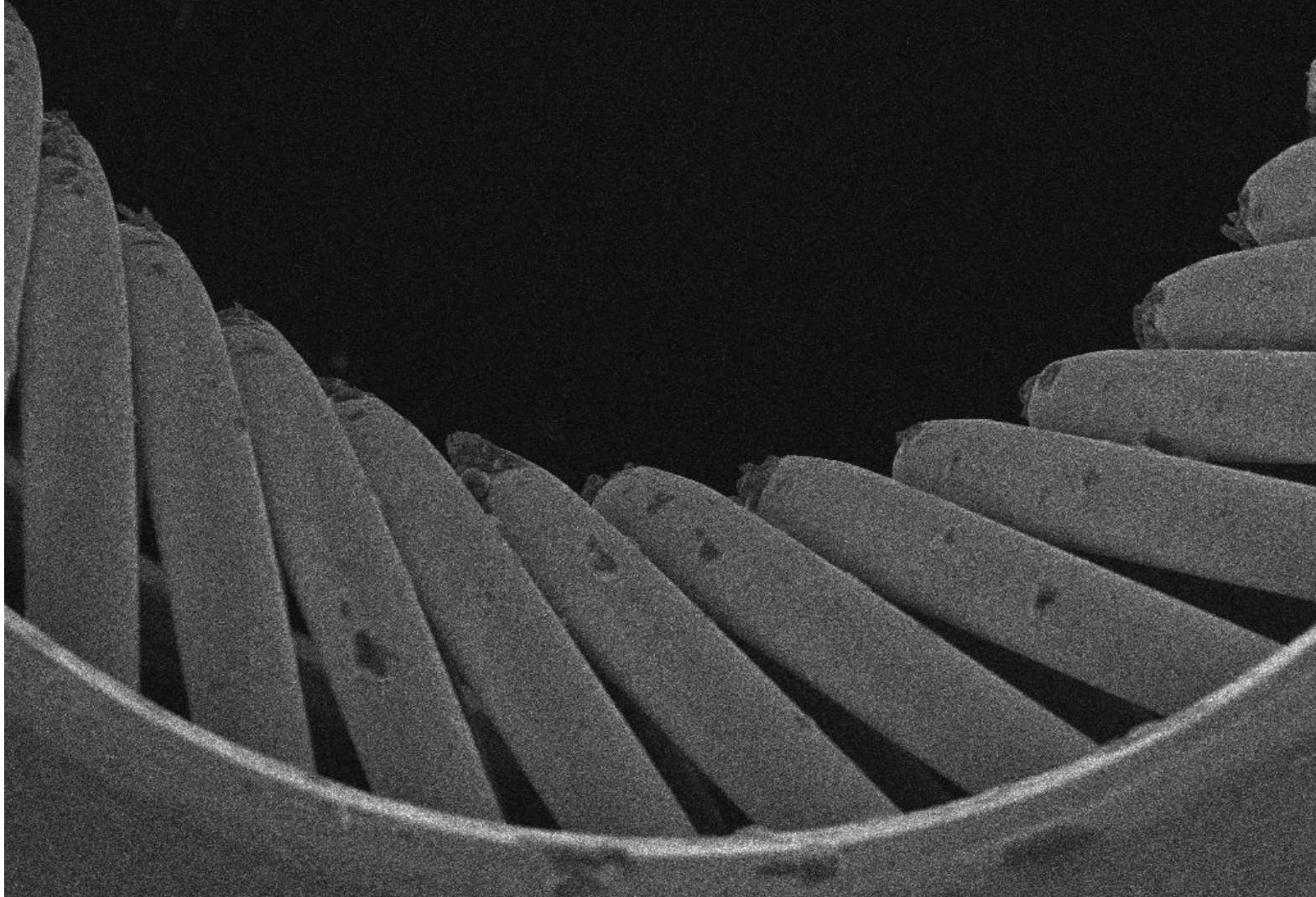
— 500 μ m —
Used Balseal Spring

BALSEAL-0

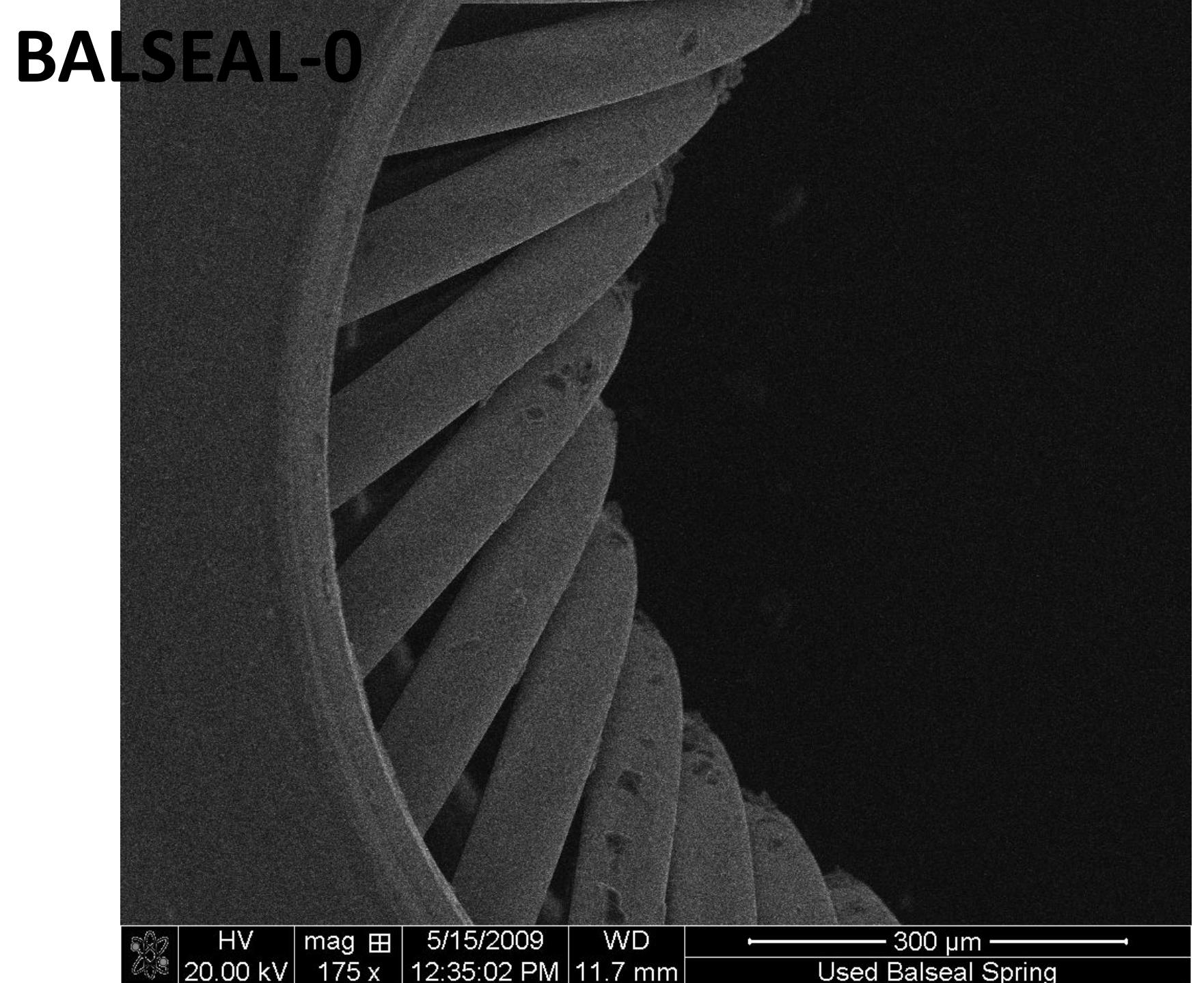


	HV 20.00 kV	mag 183 x	5/15/2009 12:31:43 PM	WD 11.2 mm	300 µm
Used Balseal Spring					

BALSEAL-0



	HV 20.00 kV	mag 172 x	5/15/2009 12:33:27 PM	WD 12.5 mm	400 µm
Used Balseal Spring					



HV
20.00 kV

mag
175 x

5/15/2009
12:35:02 PM

WD
11.7 mm

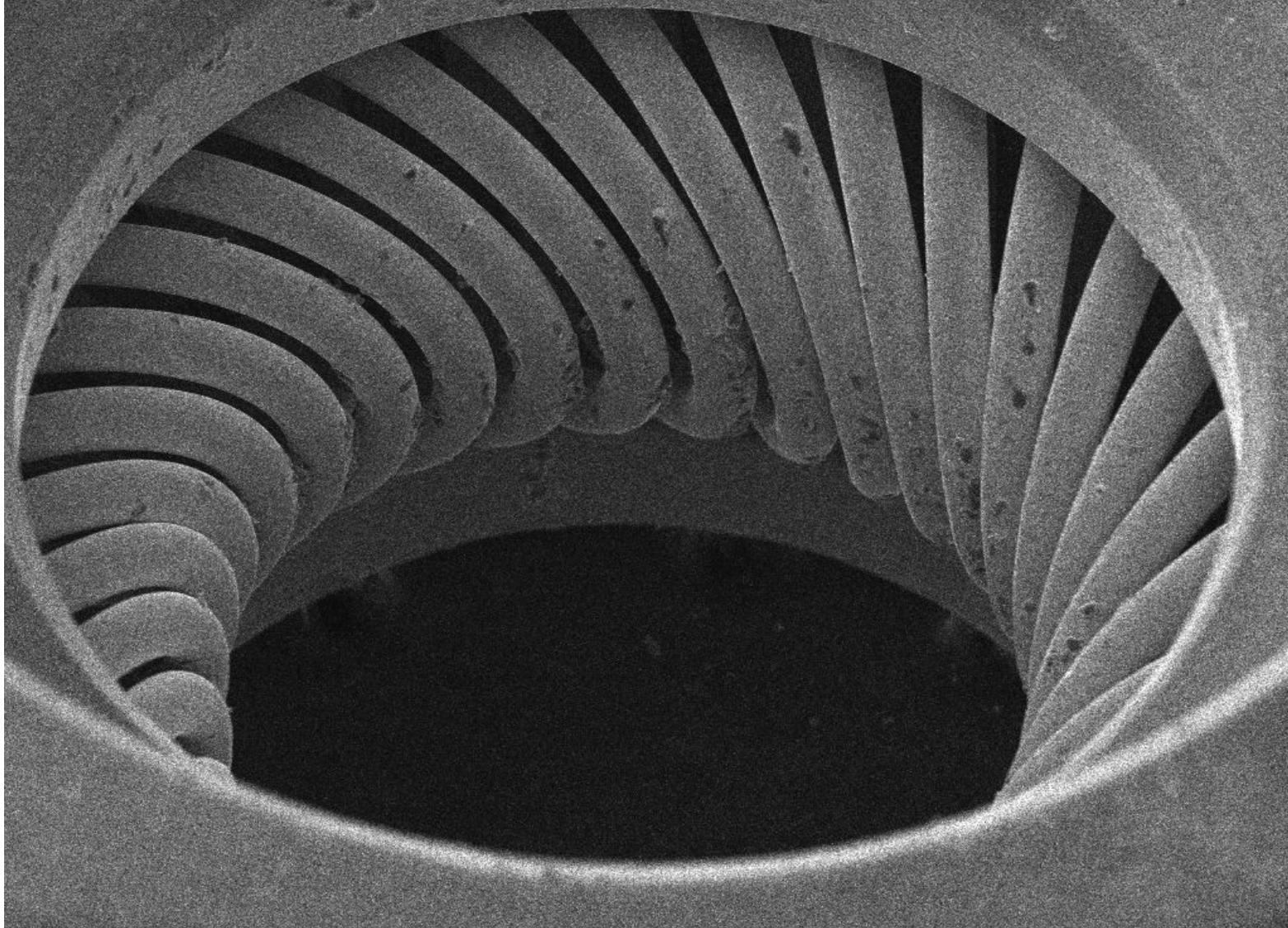
300 µm

Used Balseal Spring

BALSEAL-0



	HV 20.00 kV	mag 田 250 x	5/15/2009 12:36:40 PM	WD 11.7 mm	200 µm
Used Balseal Spring					



BALSEAL-0

	HV 20.00 kV	mag 田 100 x	5/15/2009 12:20:52 PM	WD 12.9 mm	500 µm
Used Balseal Spring					



HV
20.00 kV

mag 田
100 x

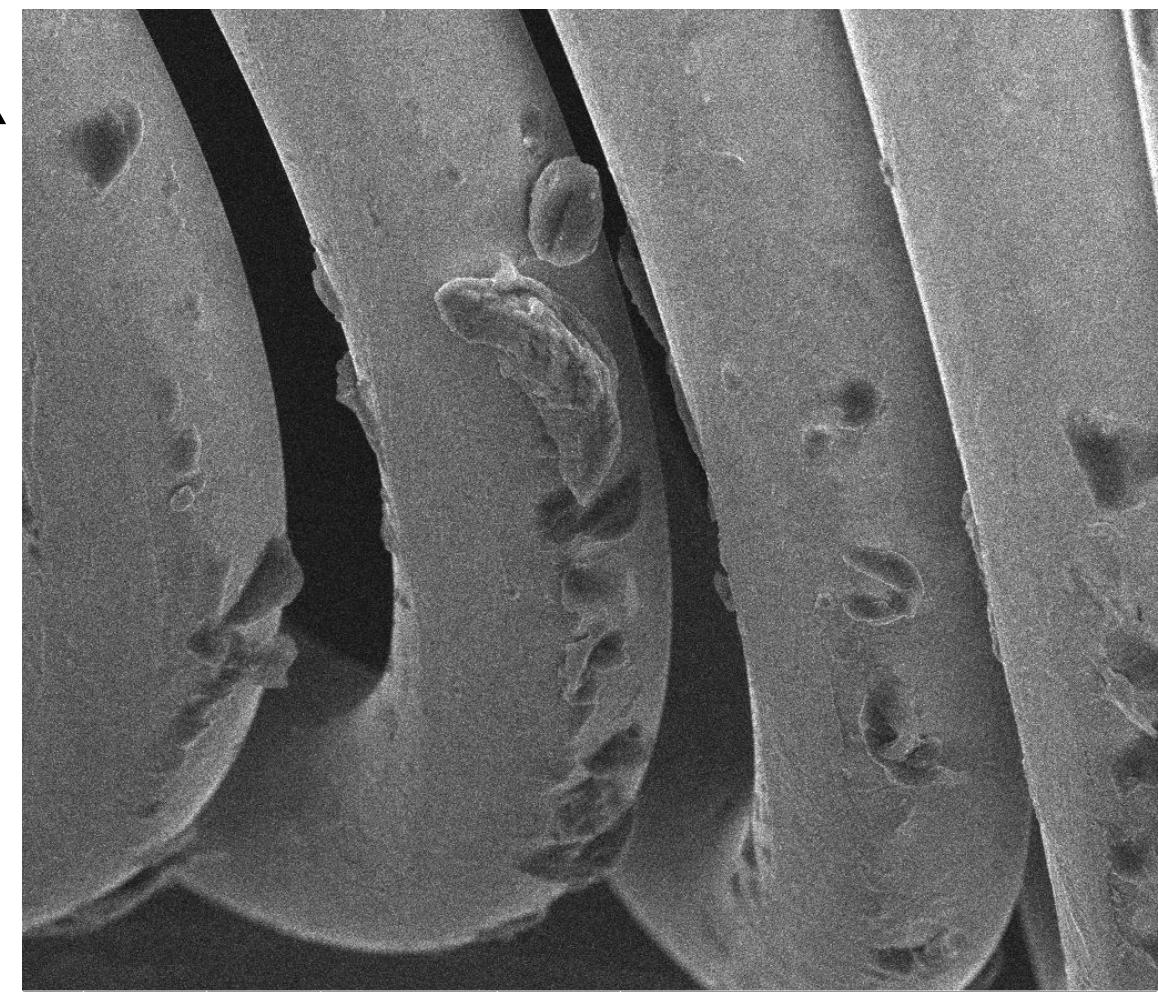
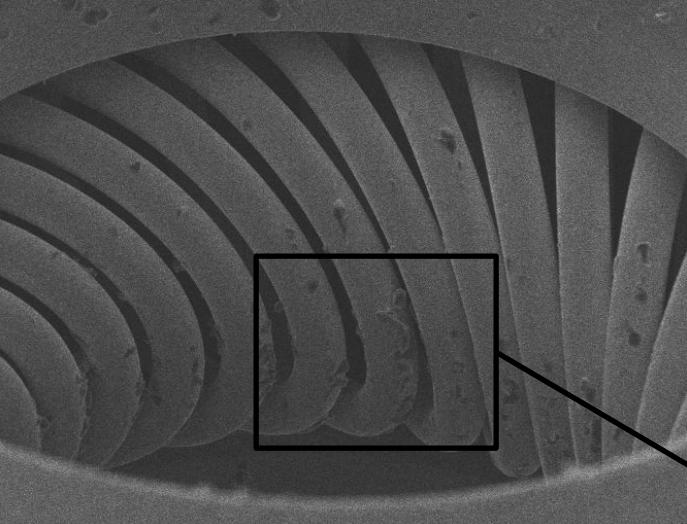
5/15/2009
11:54:56 AM

WD
13.0 mm

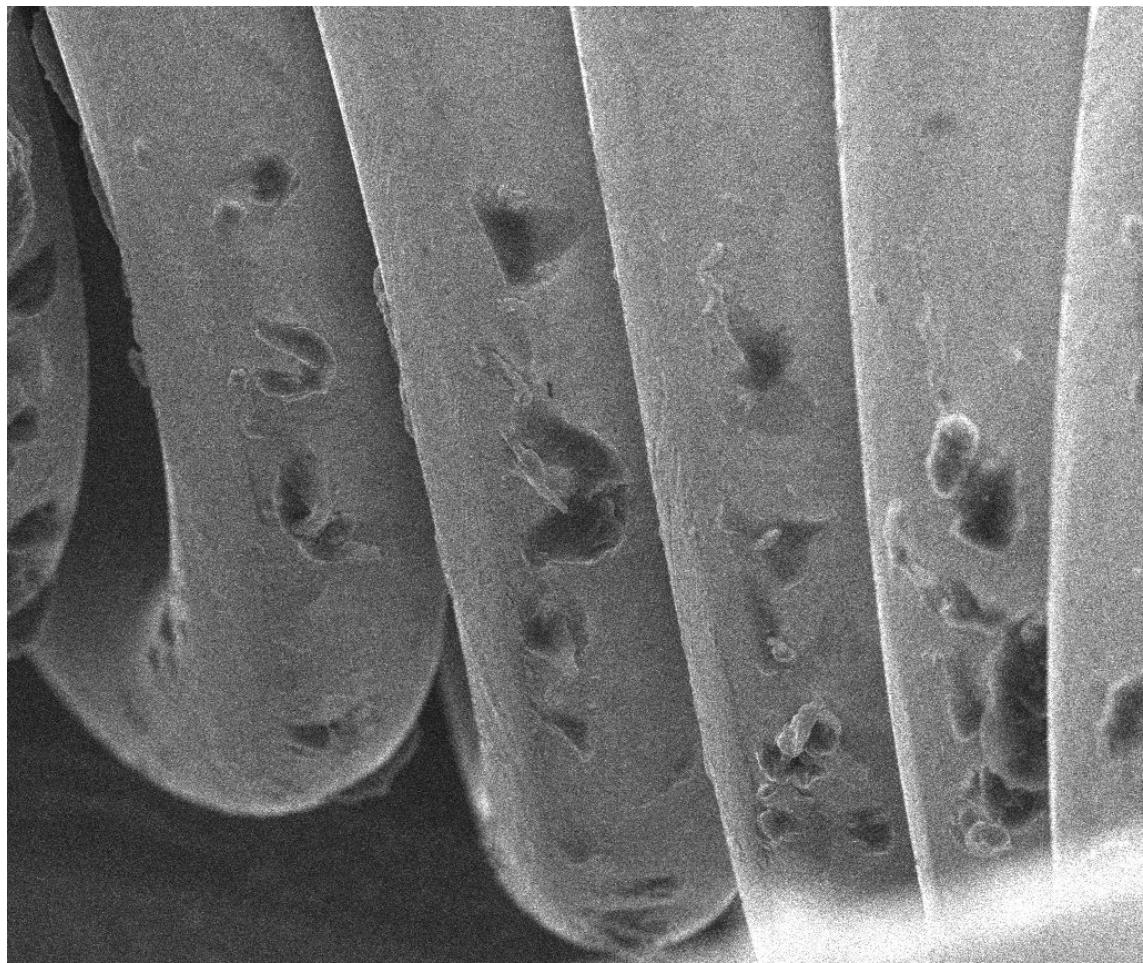
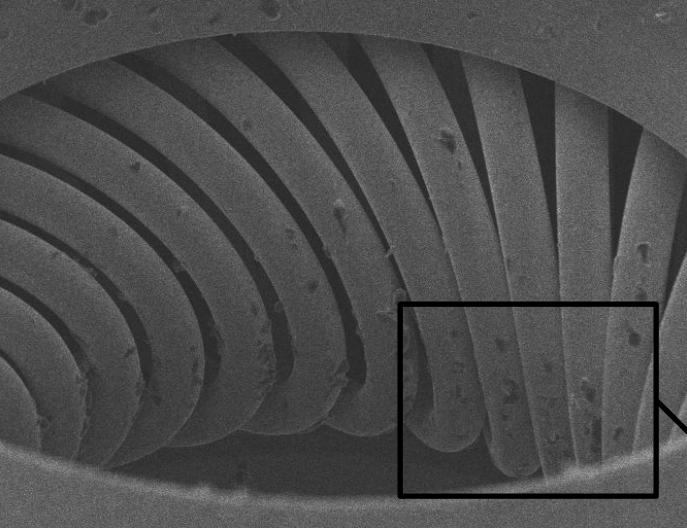
— 500 μm —

Used Balseal

BALSEAL-0

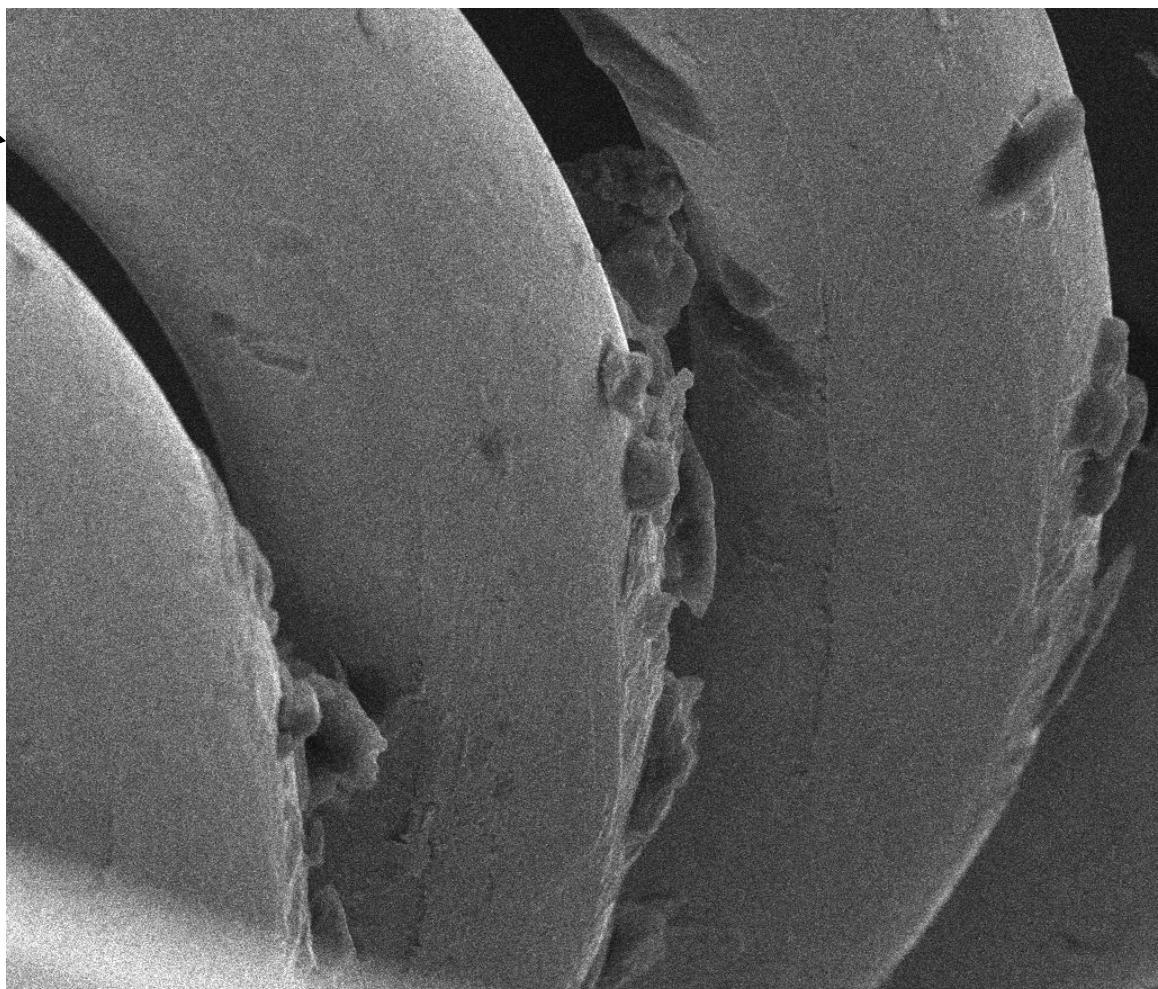
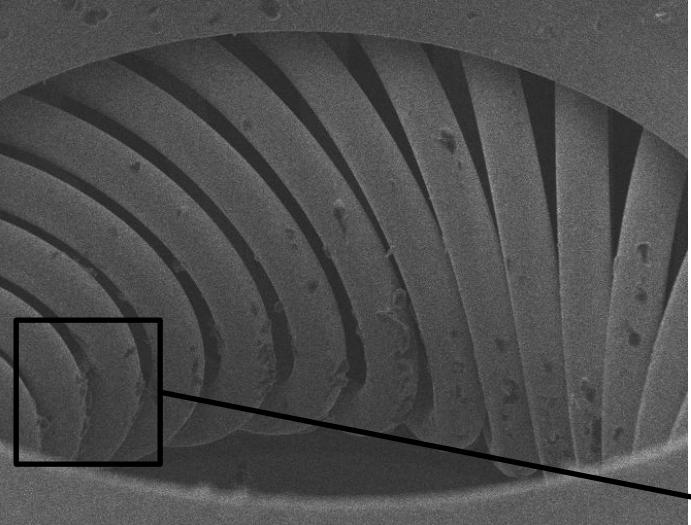


20.00 kV | HV | mag 500 x | 5/15/2009 | 12:00:18 PM | WD 13.0 mm | 100 µm | Used Balseal Spring

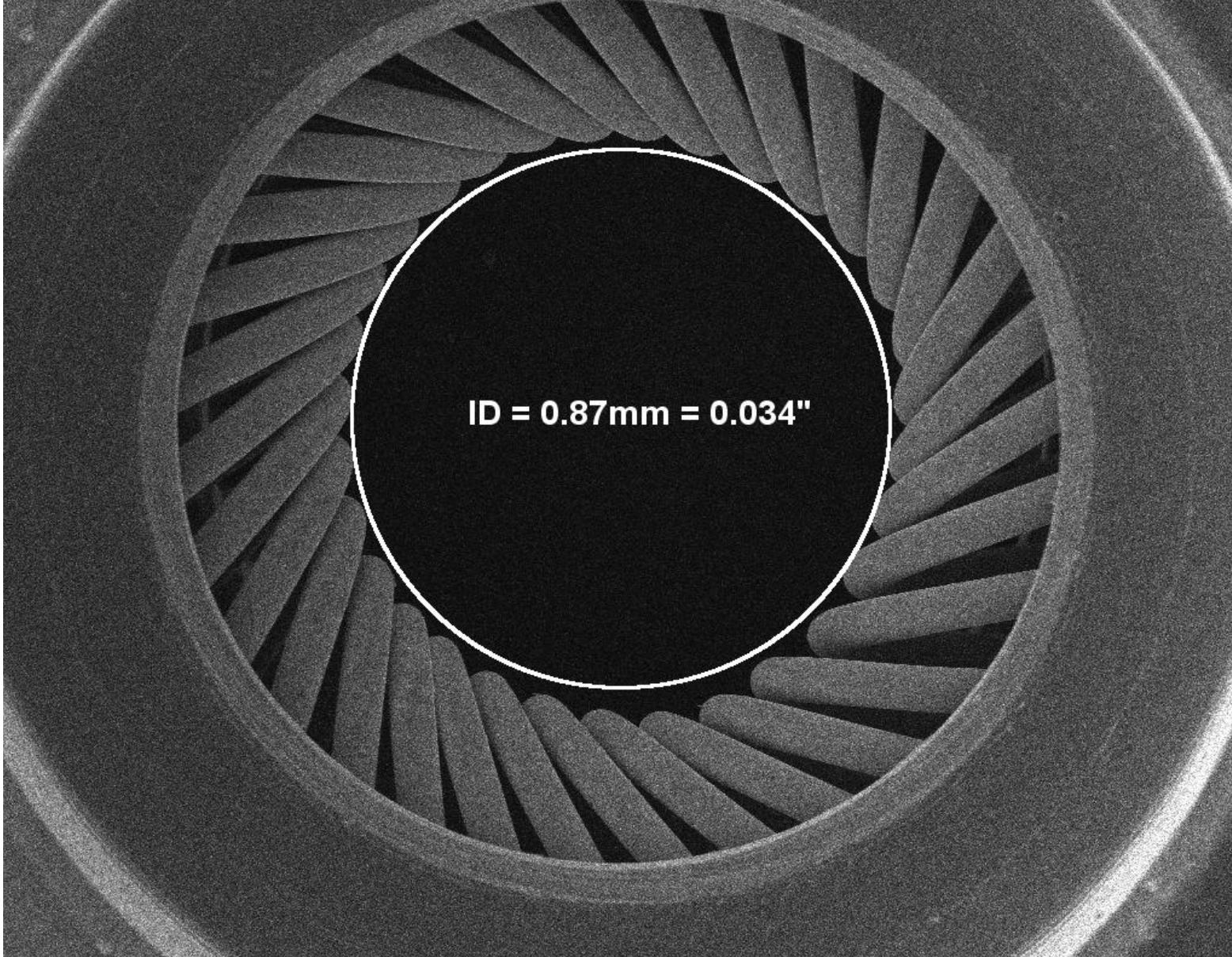


HV mag 田 5/15/2009 WD
20.00 kV 500 x 12:06:41 PM 12.9 mm

100 µm
Used Balseal Spring

HV
20.00 kVmag
750 x5/15/2009
12:08:44 PMWD
12.9 mm— 50 µm —
Used Balseal Spring

BALSEAL-1 _before testing



ID = 0.87mm = 0.034"



HV
20.00 kV

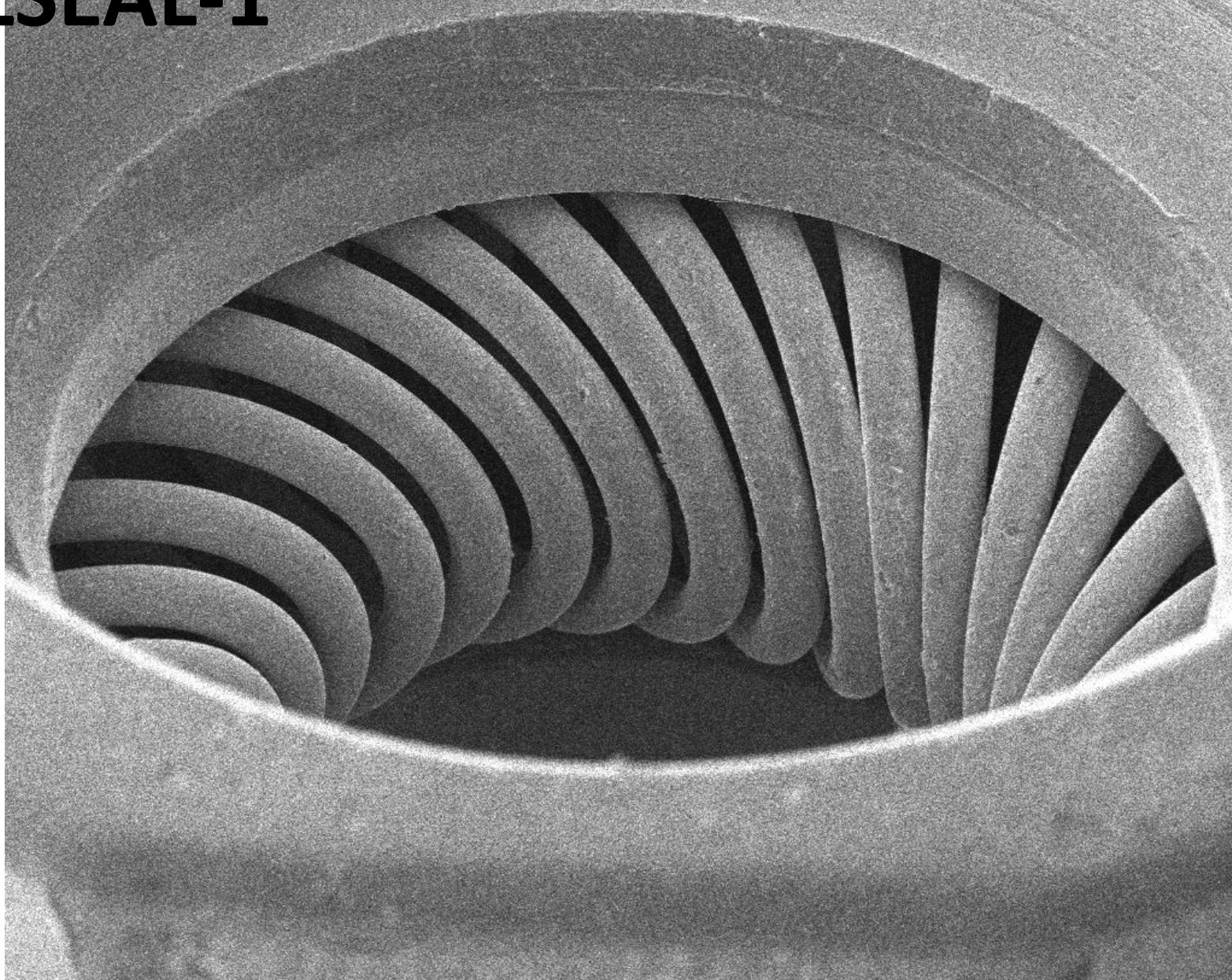
mag
75 x

5/15/2009
12:28:55 PM

WD
12.1 mm

500 µm
Pristine Balseal Spring

BALSEAL-1



HV
20.00 kV

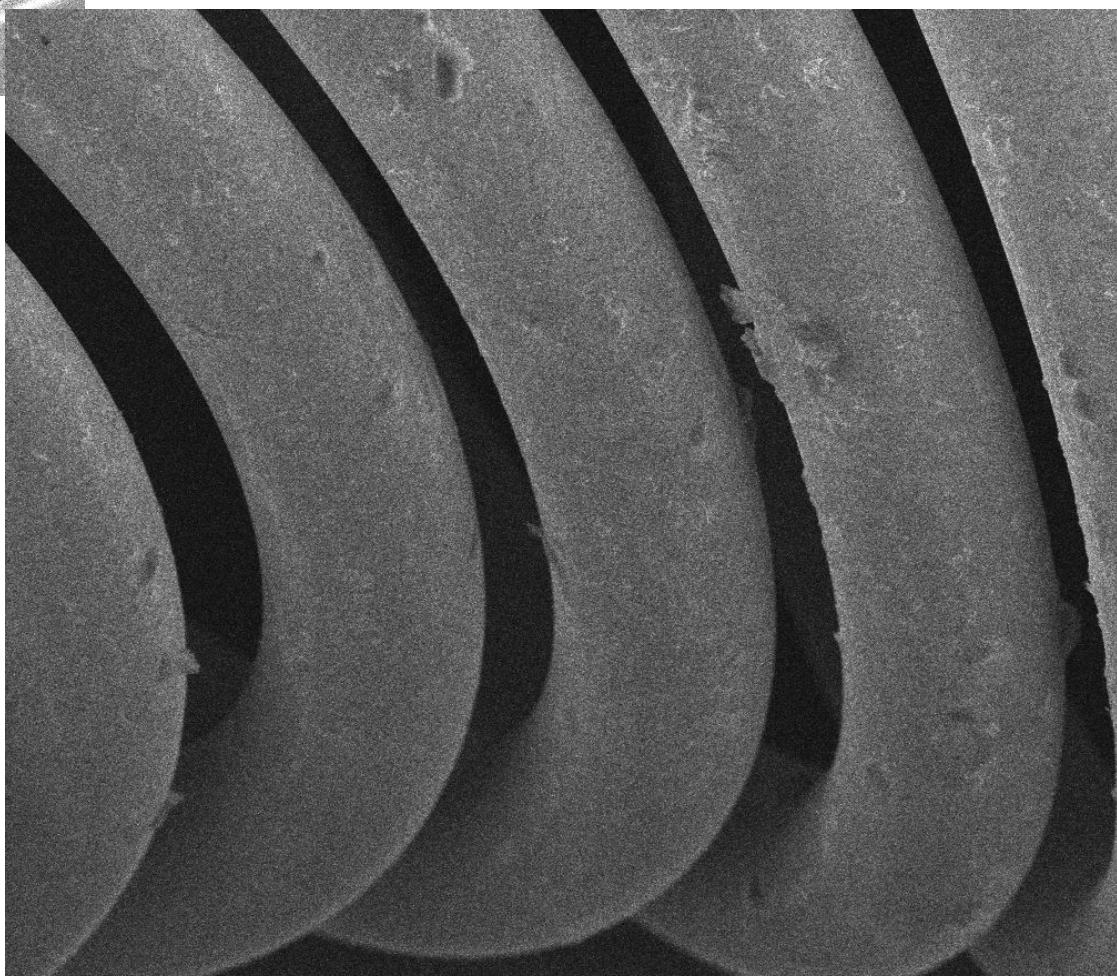
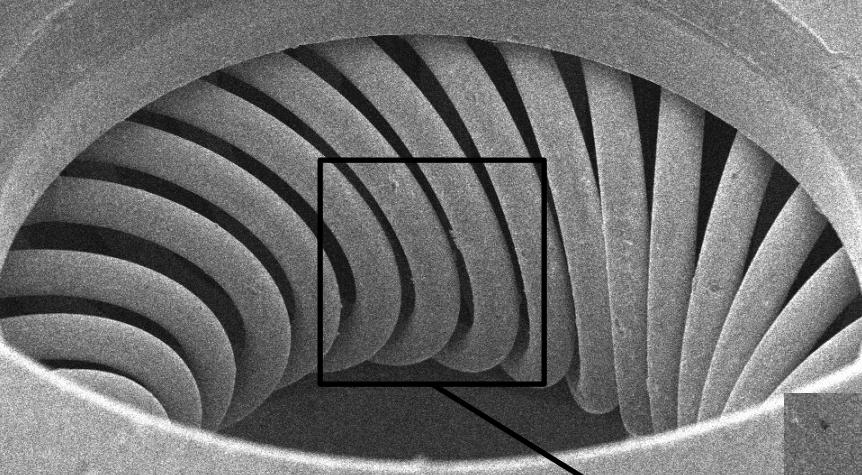
mag
100 x

5/15/2009
12:11:37 PM

WD
12.9 mm

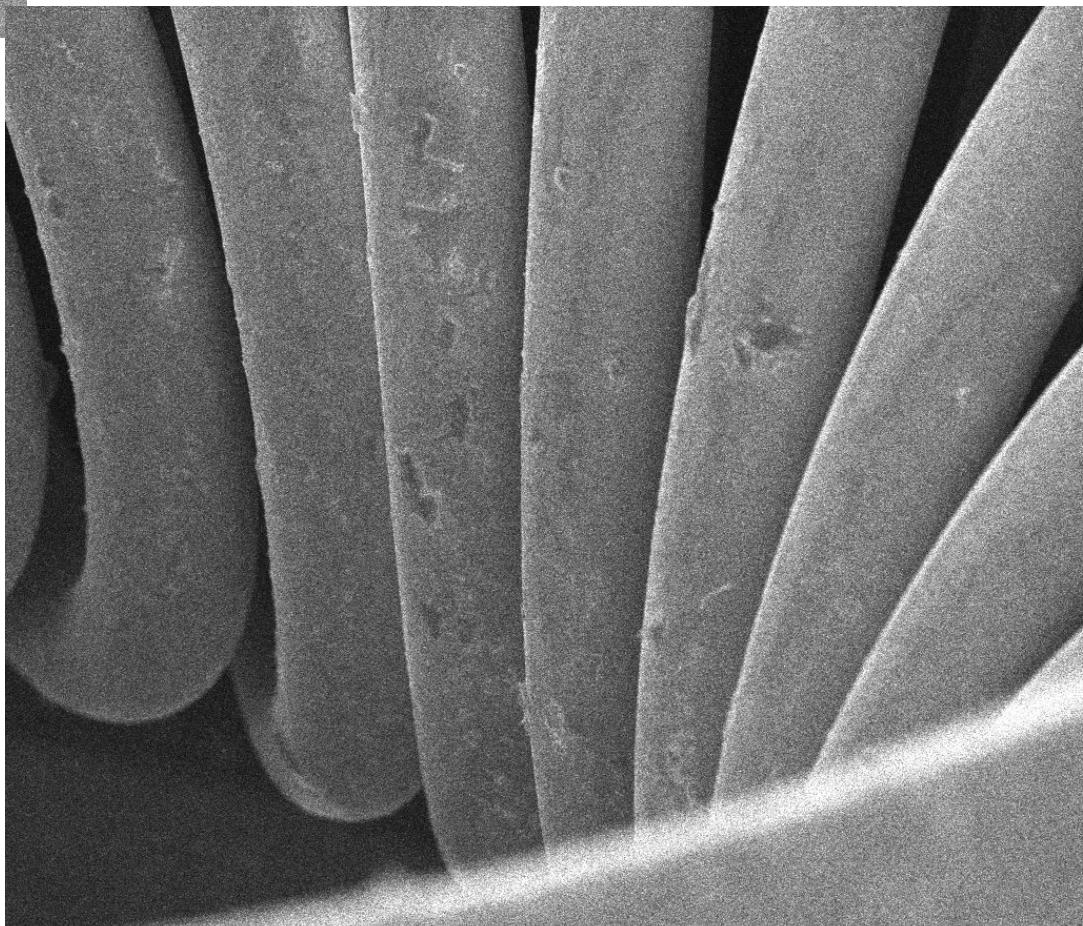
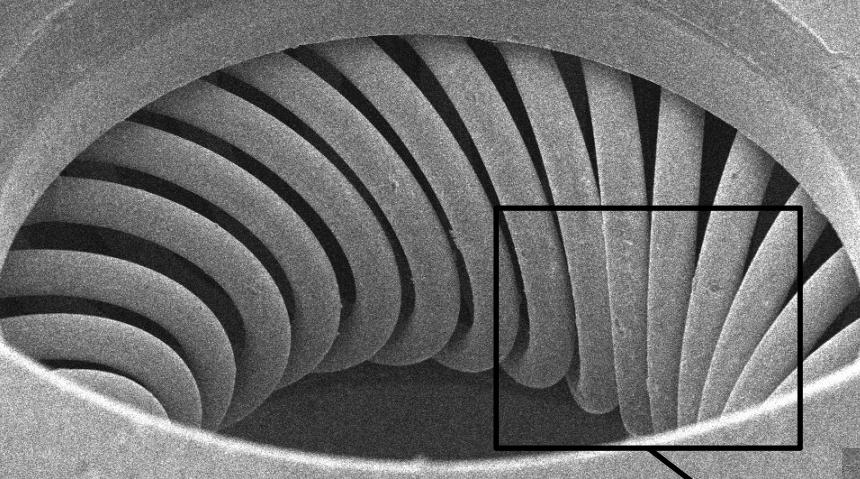
500 μm

Pristine Balseal Spring



17

	HV 20.00 kV	mag 400 x	5/15/2009 12:13:37 PM	WD 12.9 mm	— 100 µm —
					Pristine Balseal Spring



20.00 kV | HV | mag 326 x | 5/15/2009 | 12:15:35 PM | WD 12.8 mm | 200 µm | Pristine Balseal Spring

BALSEAL-1 _after force testing



ID = 0.88 mm = 0.035"



HV
20.00 kV

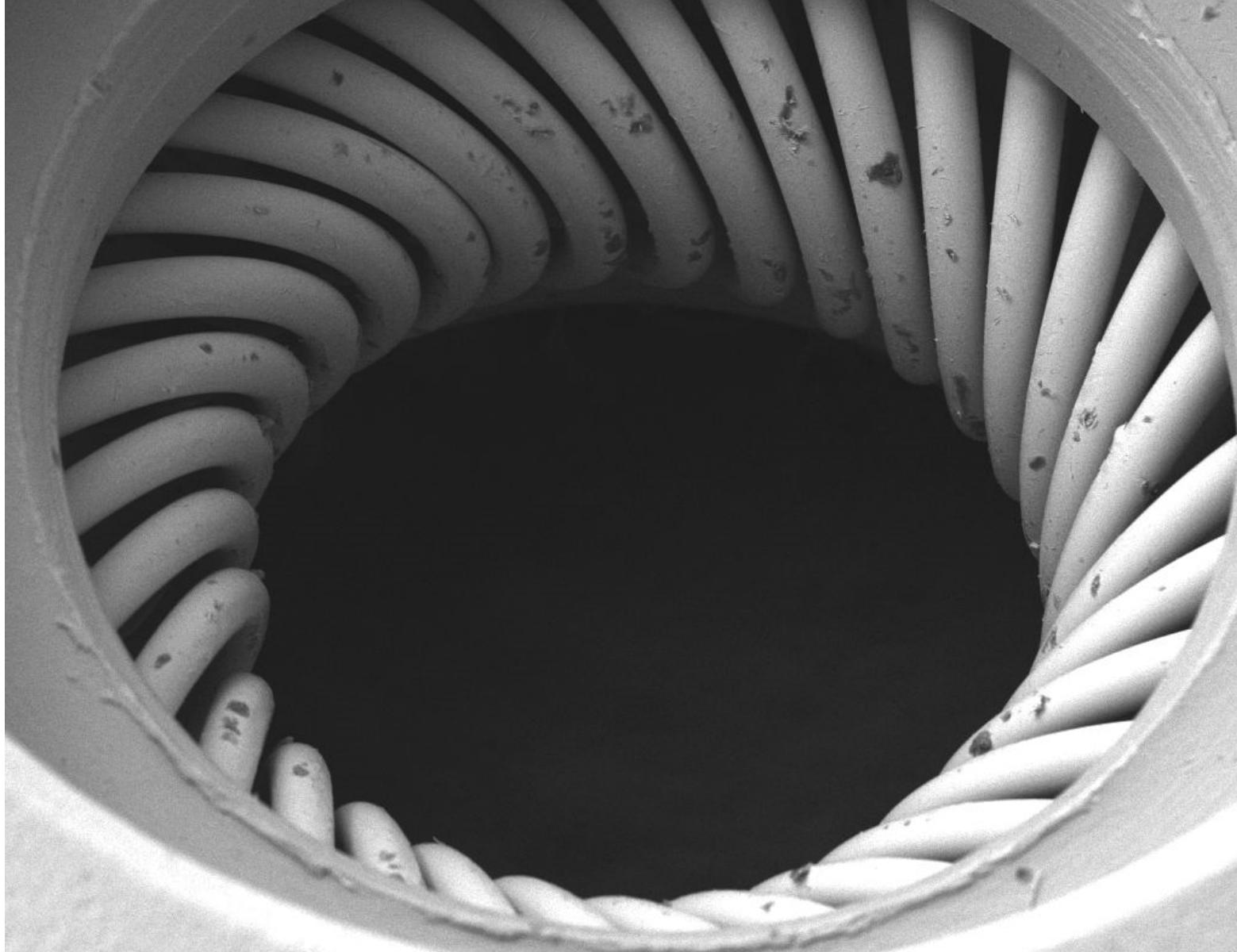
mag 田
75 x

6/1/2009
6:01:07 PM

WD
13.0 mm

— 500 µm —
BalSeal-1 after engaging through 6 grooves

BALSEAL-1 _after force testing



HV
20.00 kV

mag 田
100 x

6/1/2009
6:05:58 PM

WD
13.0 mm

500 µm

Balseal-1 after engaging through 6 grooves

BALSEAL-1 _after force testing



HV
20.00 kV

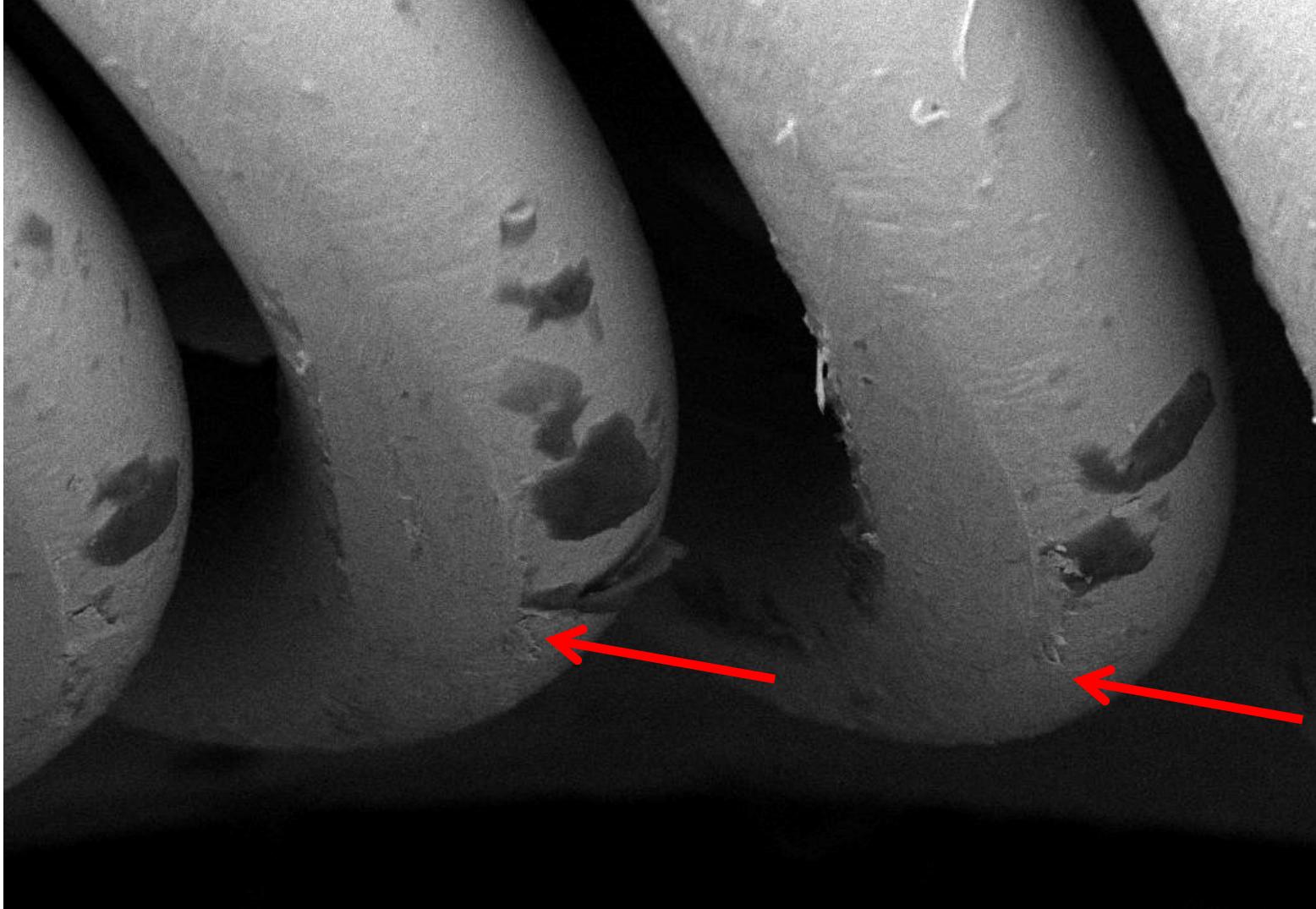
mag 田
400 x

6/1/2009
6:03:49 PM

WD
13.0 mm

100 µm
Balseal-1 after engaging through 6 grooves

BALSEAL-1 after force testing



20.00 kV

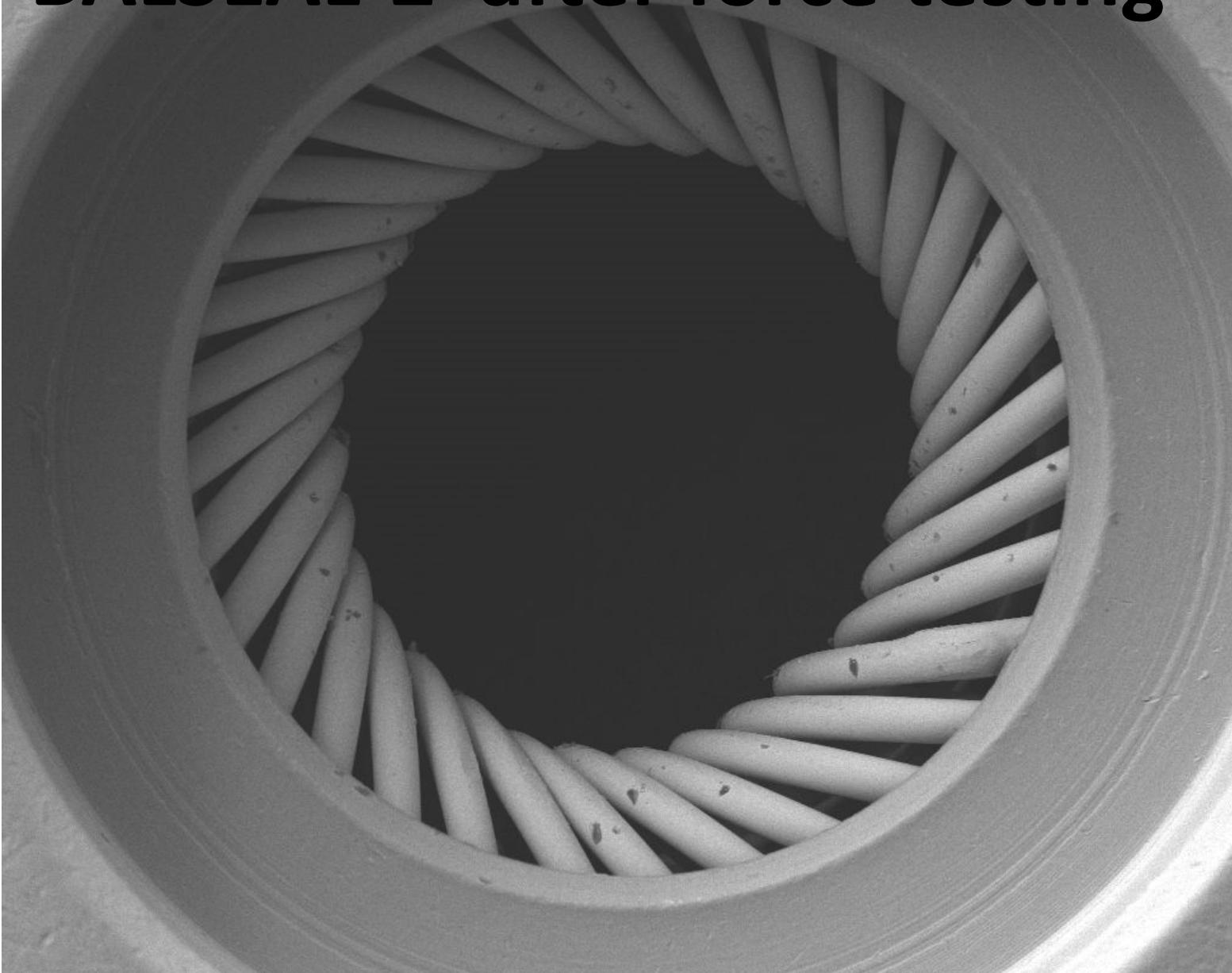
mag 590 x

6/1/2009
6:19:07 PMWD
13.0 mm

100 µm

Balseal-1 after engaging through 6 grooves

BALSEAL-2 after force testing



HV
20.00 kV

mag
75 x

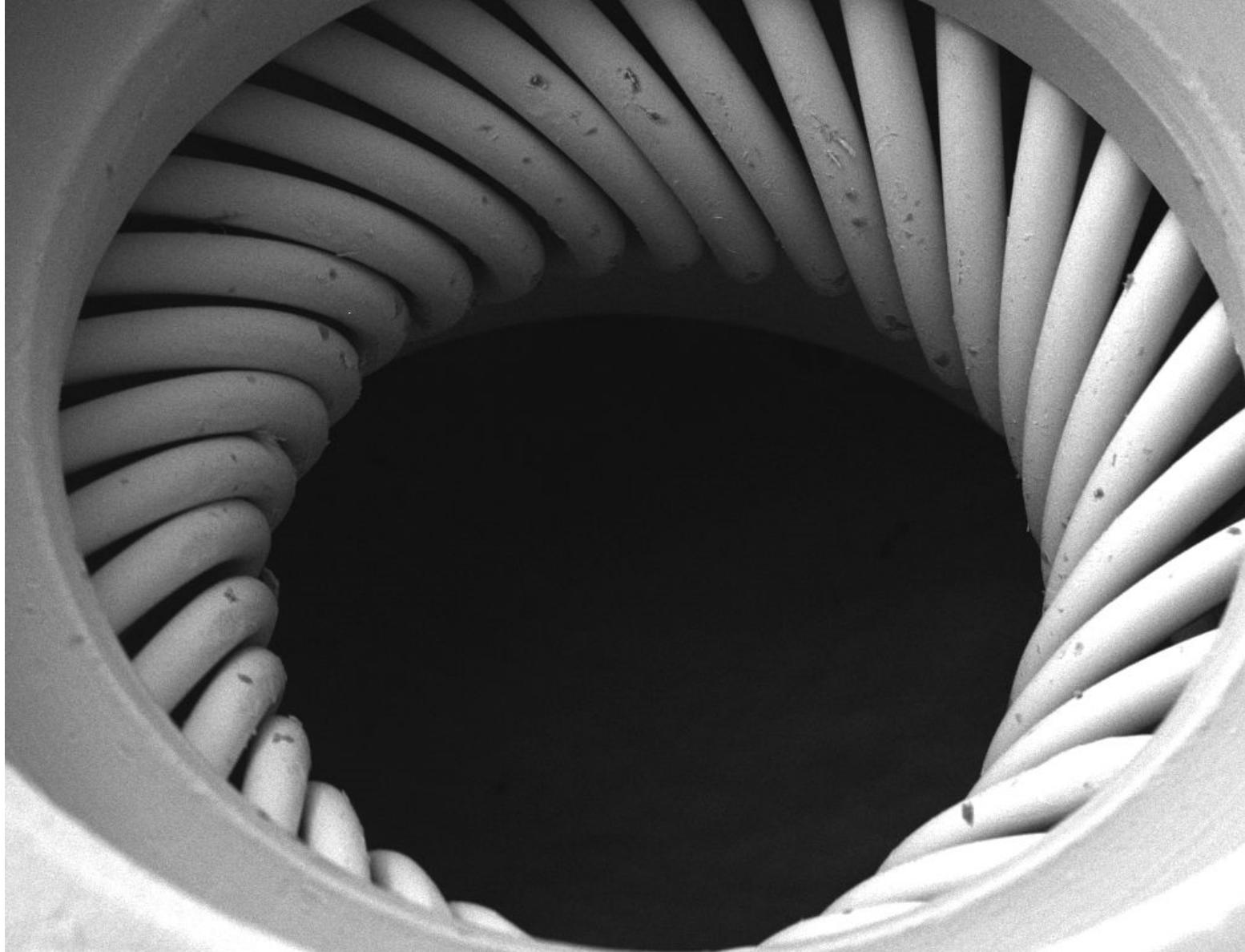
6/1/2009
6:07:32 PM

WD
13.0 mm

— 500 µm —

Balseal-2 after engaging through 6 grooves

BALSEAL-2 after force testing



HV
20.00 kV

mag 田
100 x

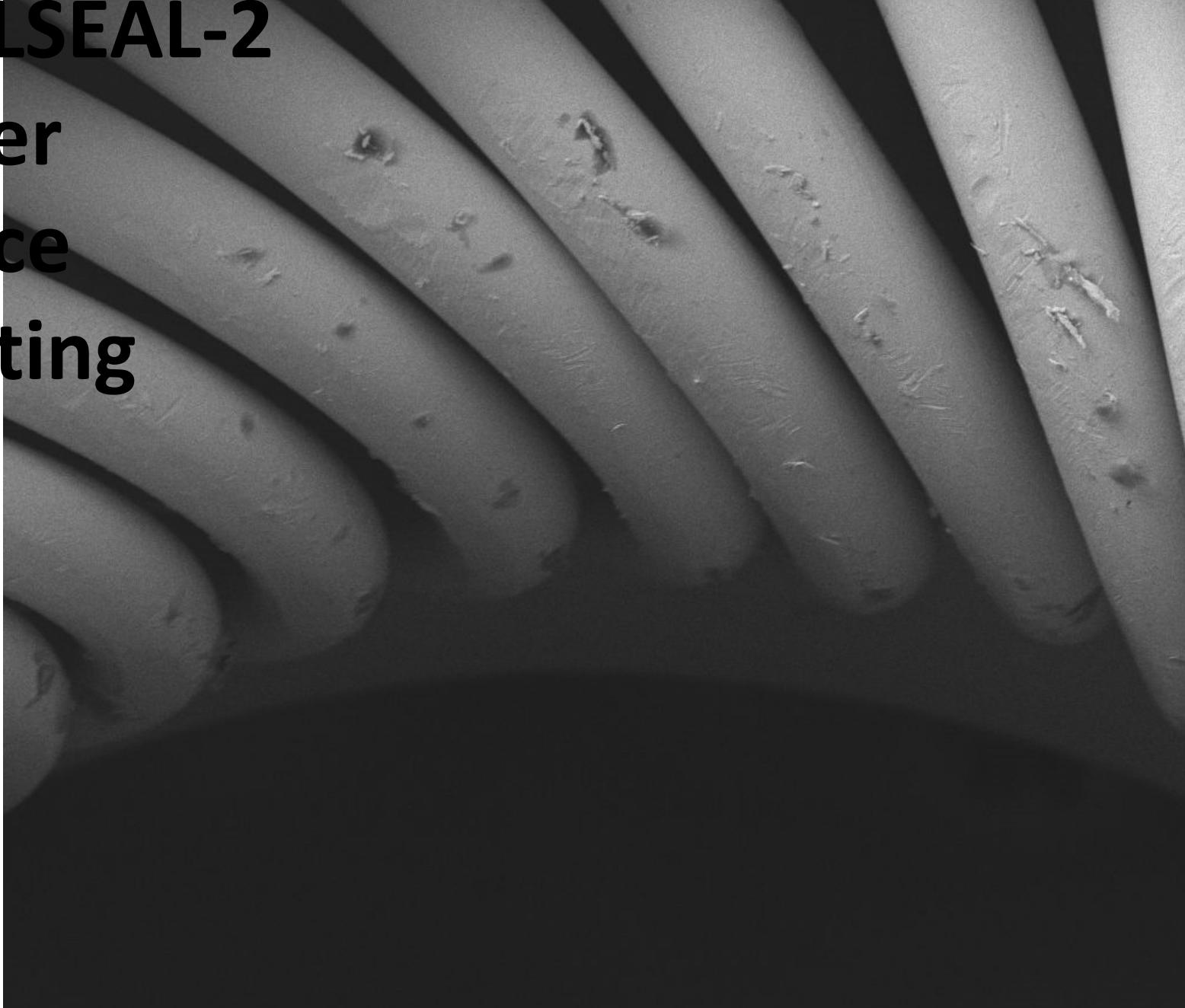
6/1/2009
6:11:12 PM

WD
13.0 mm

500 µm

Balseal-2 after engaging through 6 grooves

BALSEAL-2 after force testing



HV
20.00 kV

mag
250 x

6/1/2009
6:13:20 PM

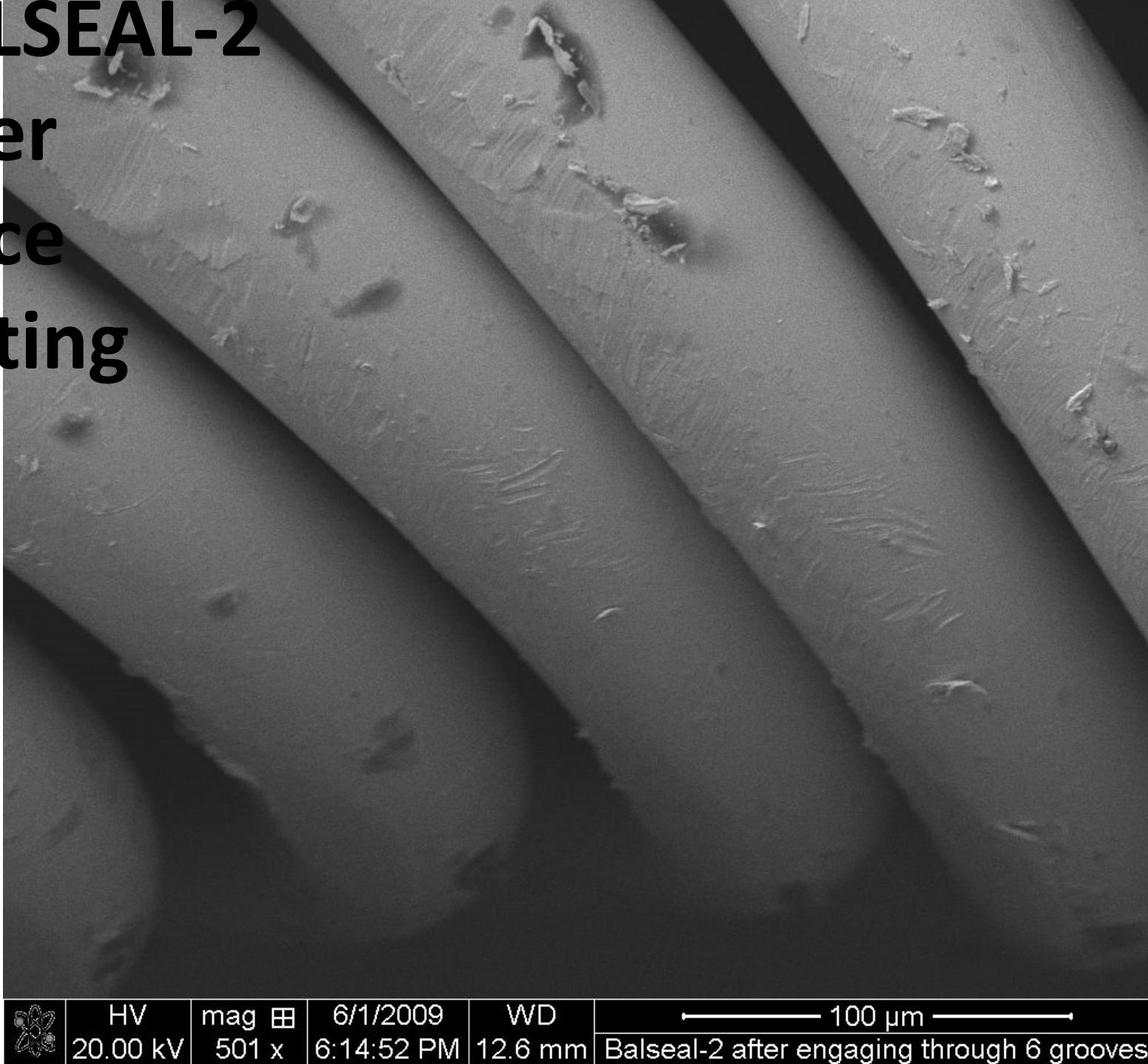
WD
12.6 mm

200 µm

Balseal-2 after engaging through 6 grooves

BALSEAL-2

after
force
testing

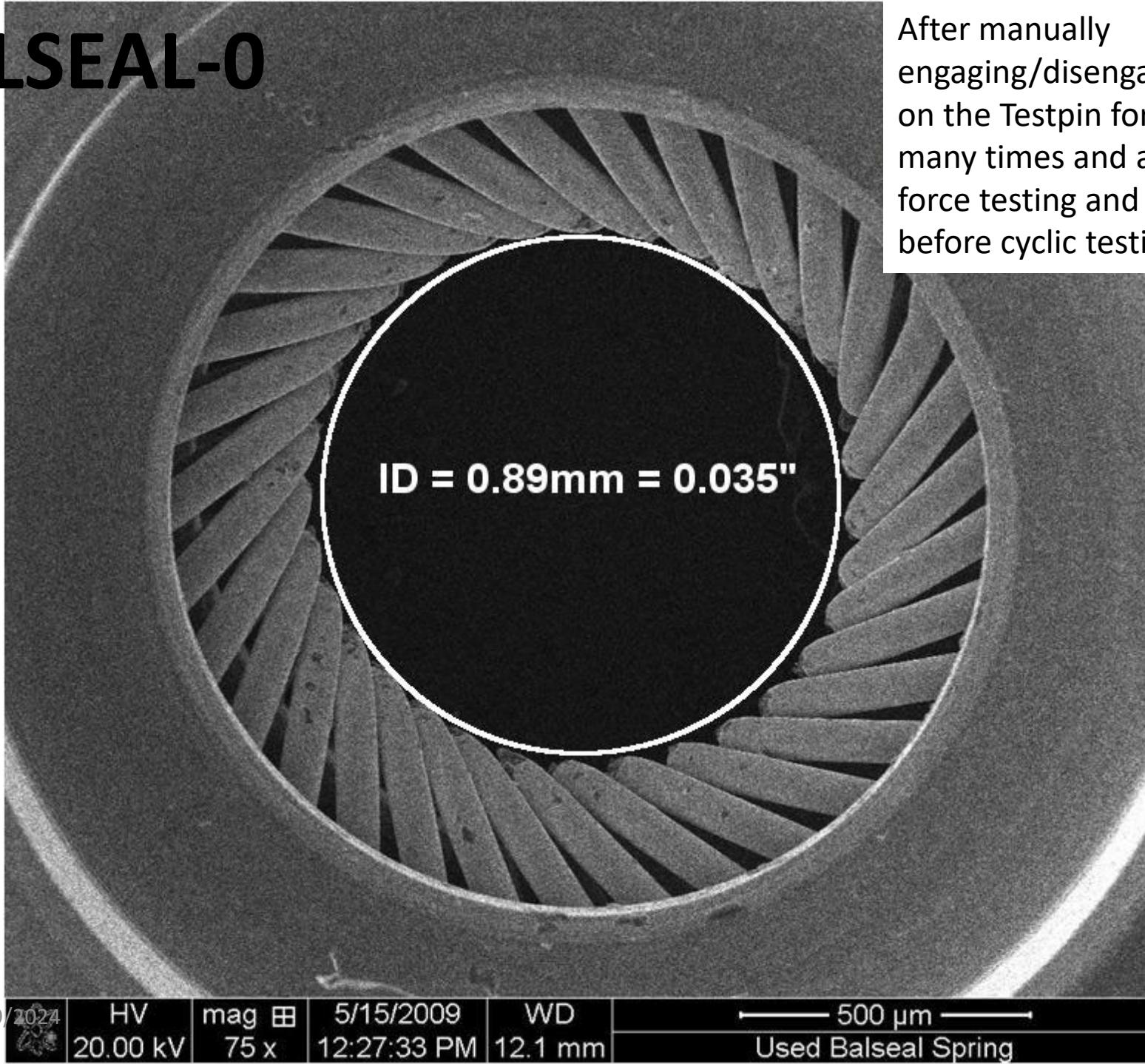


	HV 20.00 kV	mag 田 501 x	6/1/2009 6:14:52 PM	WD 12.6 mm	100 µm	Balseal-2 after engaging through 6 grooves
--	----------------	----------------	------------------------	---------------	--------	--



Appendix 2

BALSEAL-0



After manually engaging/disengaging on the Testpin for many times and after force testing and before cyclic testing

6/19/2024



HV
20.00 kV

mag
75 x

5/15/2009
12:27:33 PM

WD
12.1 mm

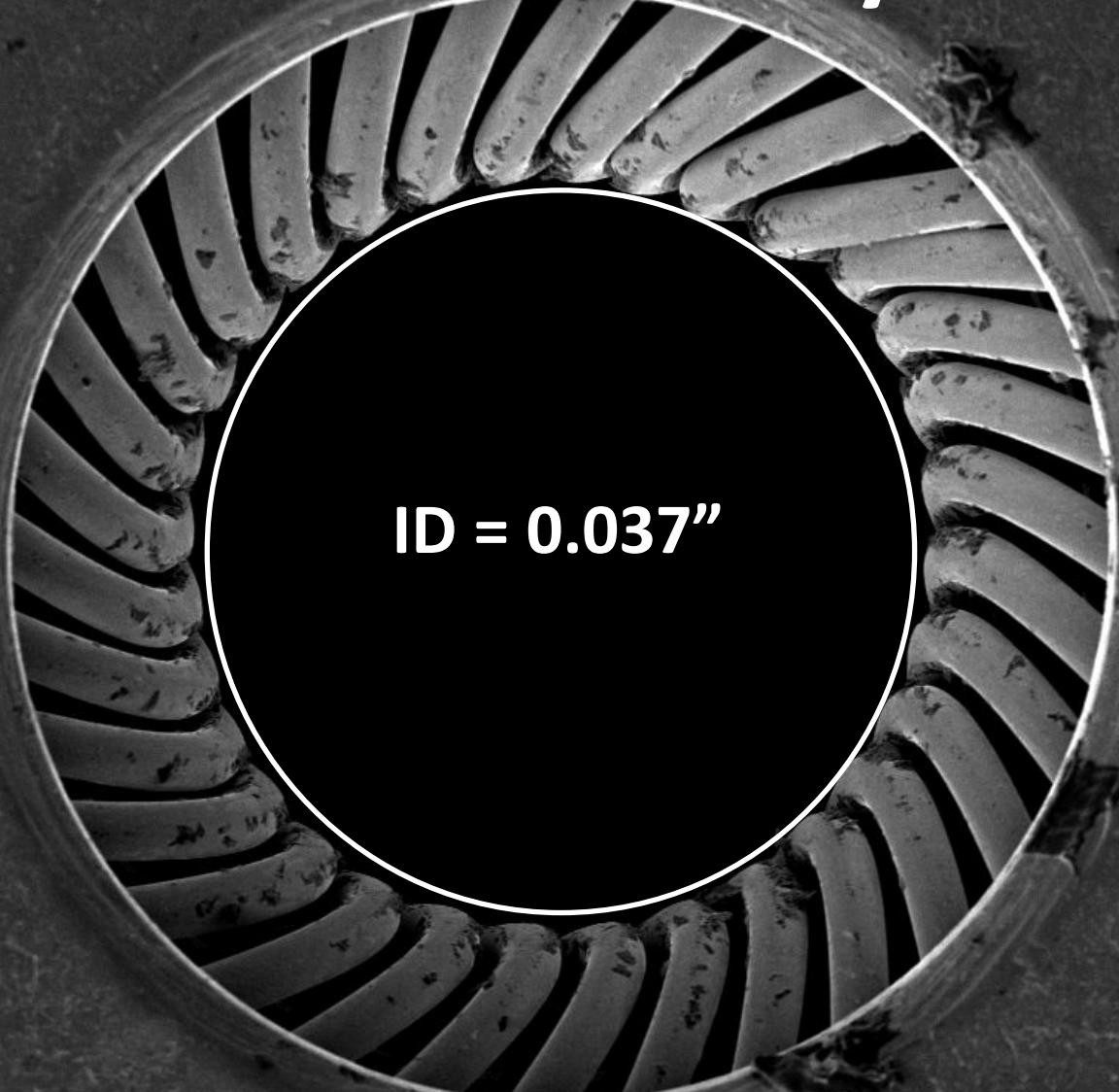
— 500 µm —

Used Balseal Spring

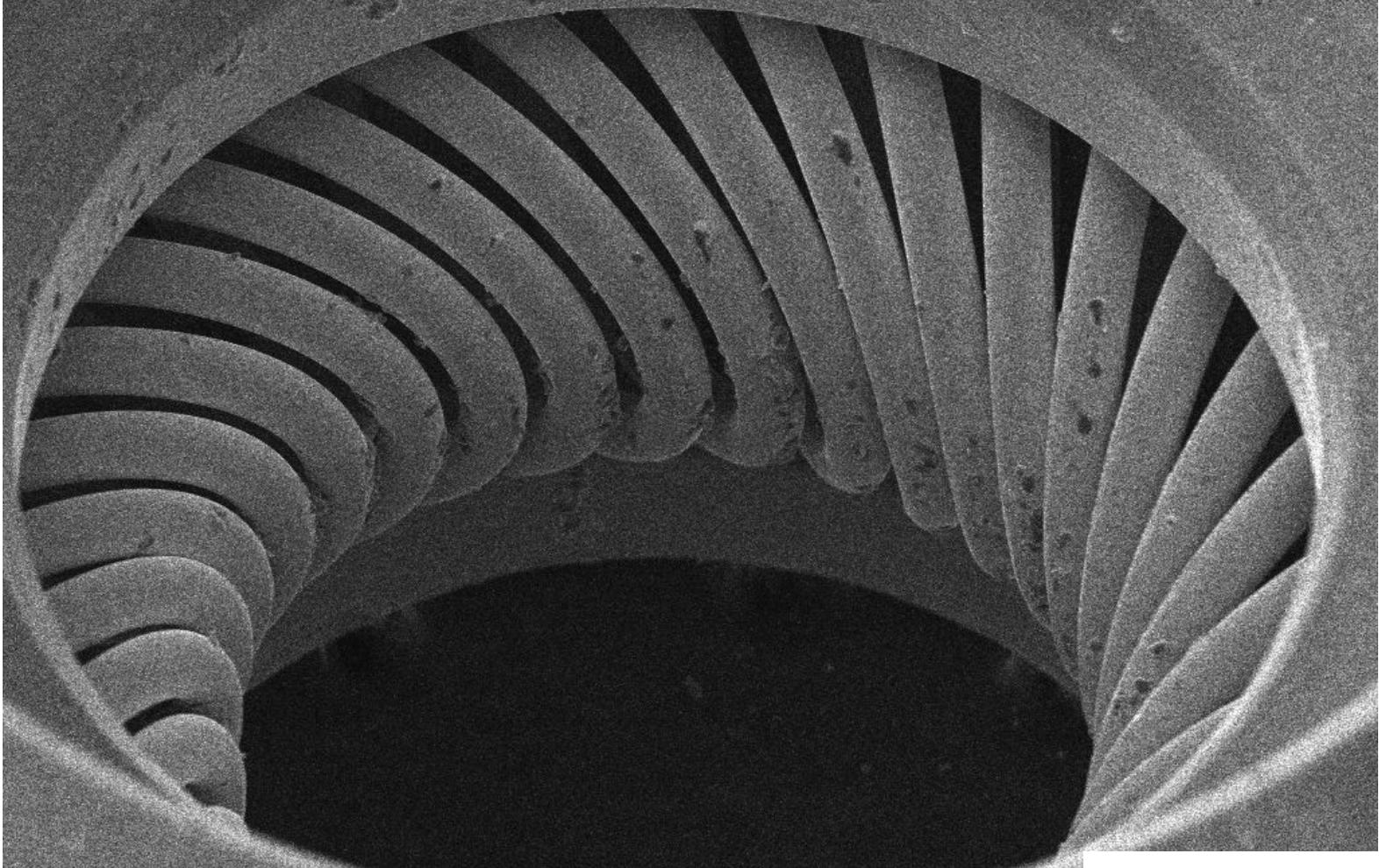
BALSEAL-0 _after 20 cycles

ID = 0.035"

Balseal-0 after 70 cycles



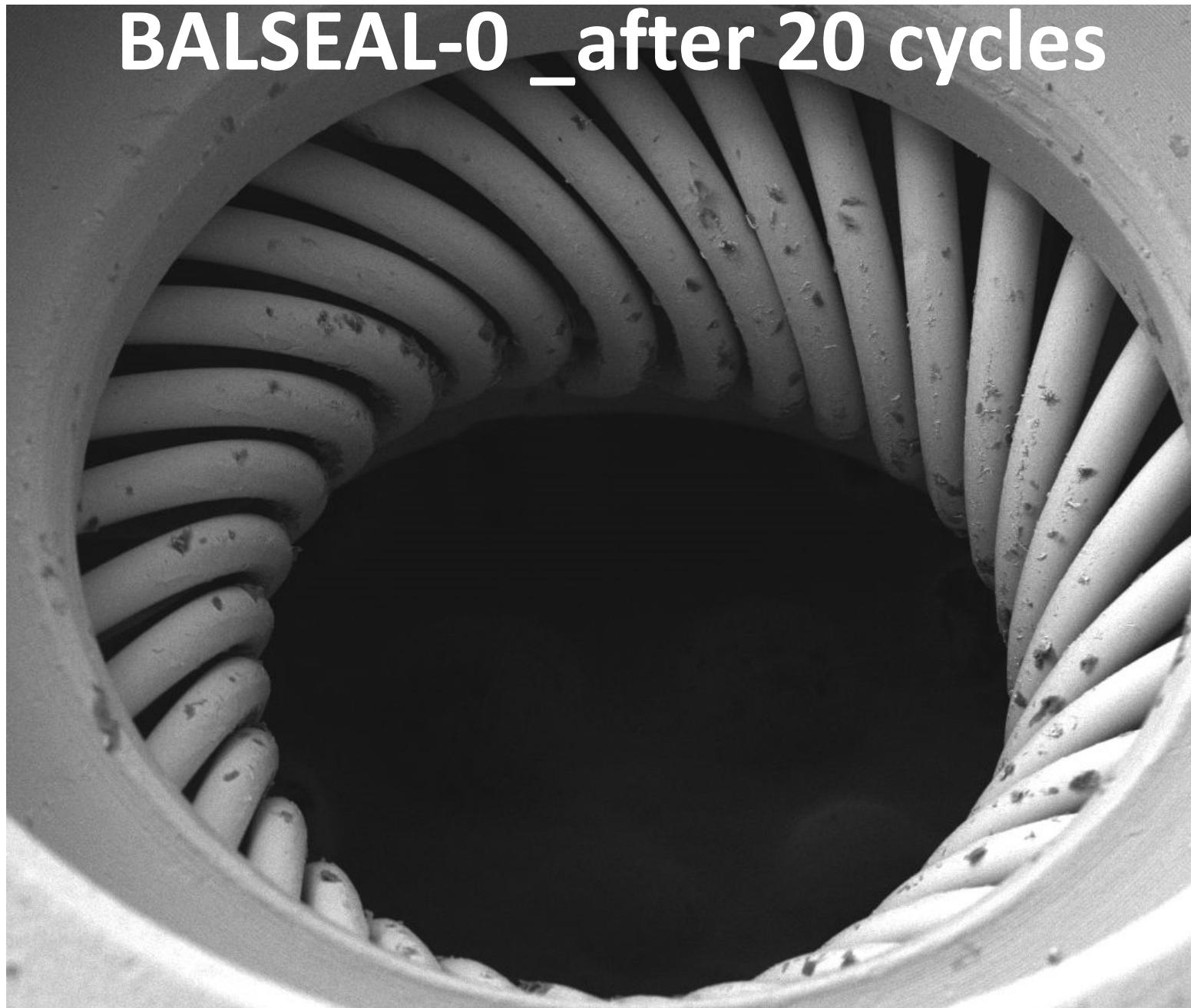
ID = 0.037"



BALSEAL-0

After manually
engaging/disengaging
on the Testpin for
many times and after
force testing and
before cyclic testing

BALSEAL-0 _after 20 cycles



6/19/2024
20.00 kV

HV
20.00 kV

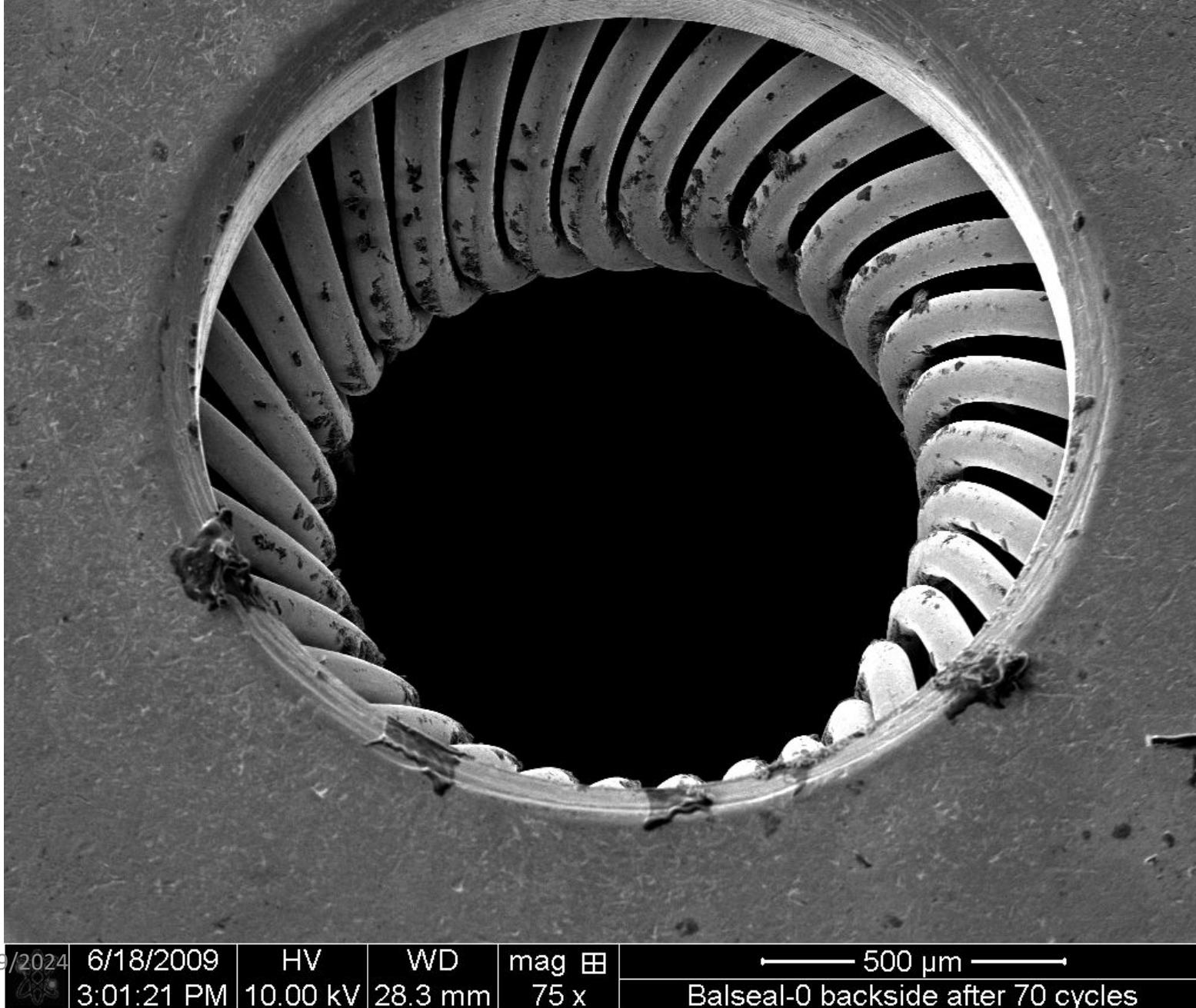
mag
100 x

6/1/2009
5:57:14 PM

WD
13.0 mm

500 µm
BALSEAL-0 after many tests

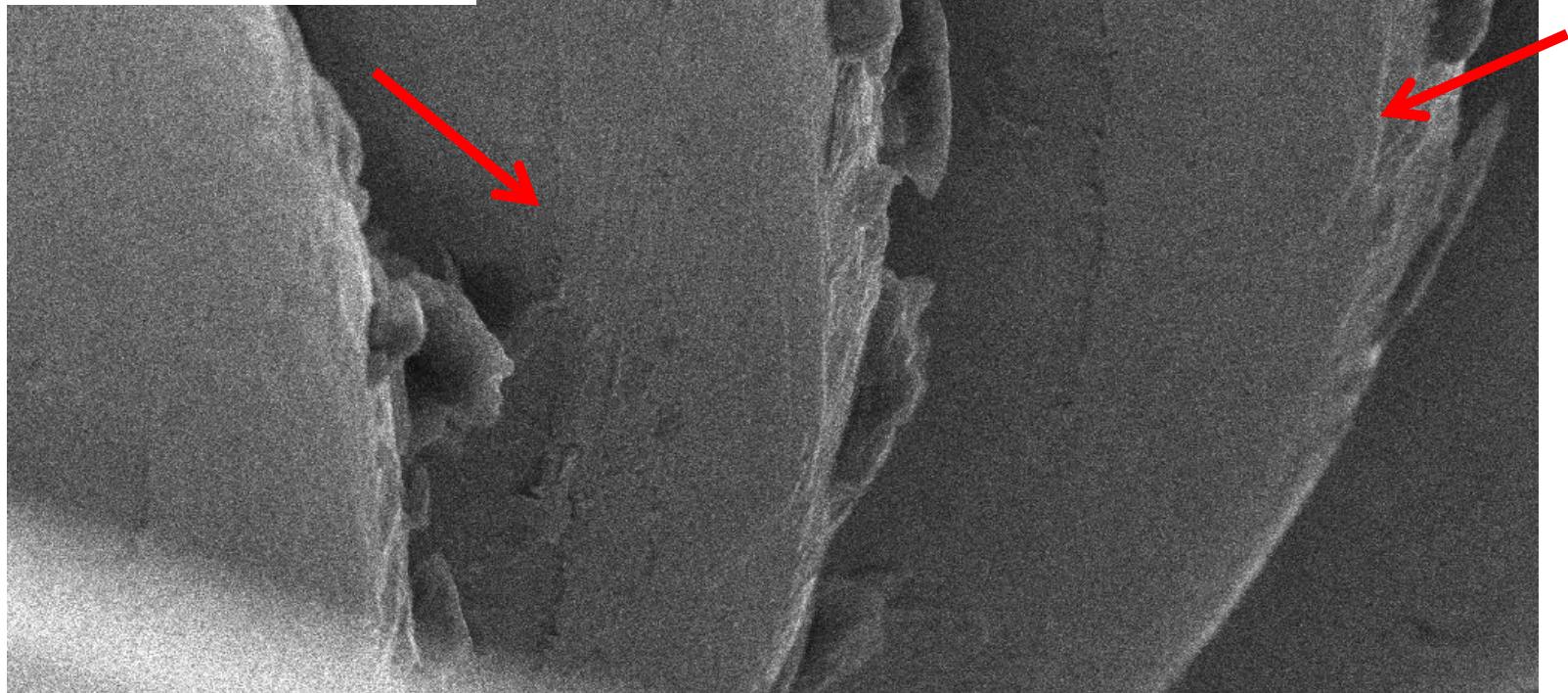
BALSEAL-0 _ after 70 cycles



6/19/2024	6/18/2009	HV	WD	mag 田	500 µm
3:01:21 PM		10.00 kV	28.3 mm	75 x	Balseal-0 backside after 70 cycles

BALSEAL- 0

After manually
engaging/disengaging
on the Testpin for
many times and after
force testing and
before cyclic testing



6/19/2024	HV 20.00 kV	mag 750 x	5/15/2009 12:08:44 PM	WD 12.9 mm	— 50 µm —
Used Balseal Spring				Used Balseal Spring	

BALSEAL-0 _after 20 cycles



6/19/2024

HV
20.00 kV

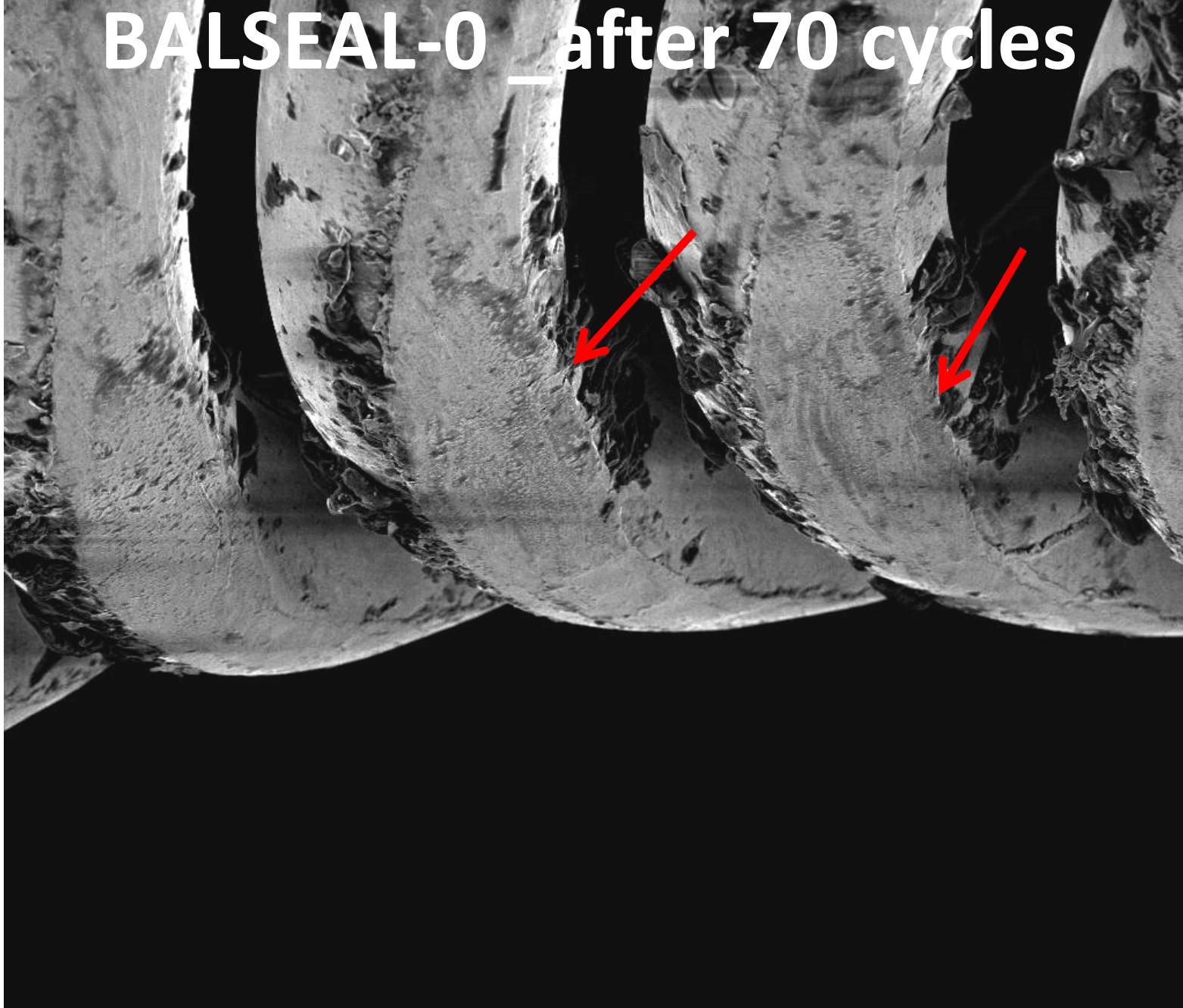
mag
501 x

6/1/2009
6:22:33 PM

WD
12.9 mm

100 µm
Balseal-0 after many tests

BALSEAL-0 _after 70 cycles



6/19/2024
 6:58:57 PM

6/18/2009
2:58:57 PM

HV
10.00 kV

WD
28.3 mm

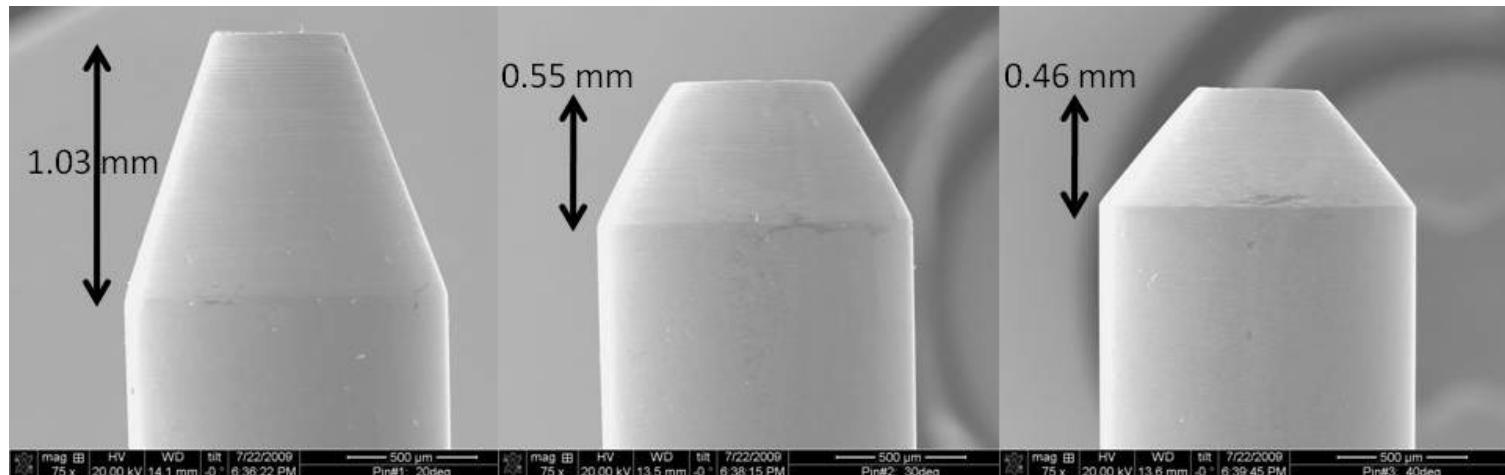
mag
500 x

100 µm
Balseal-0 backside after 70 cycles



Appendix 3

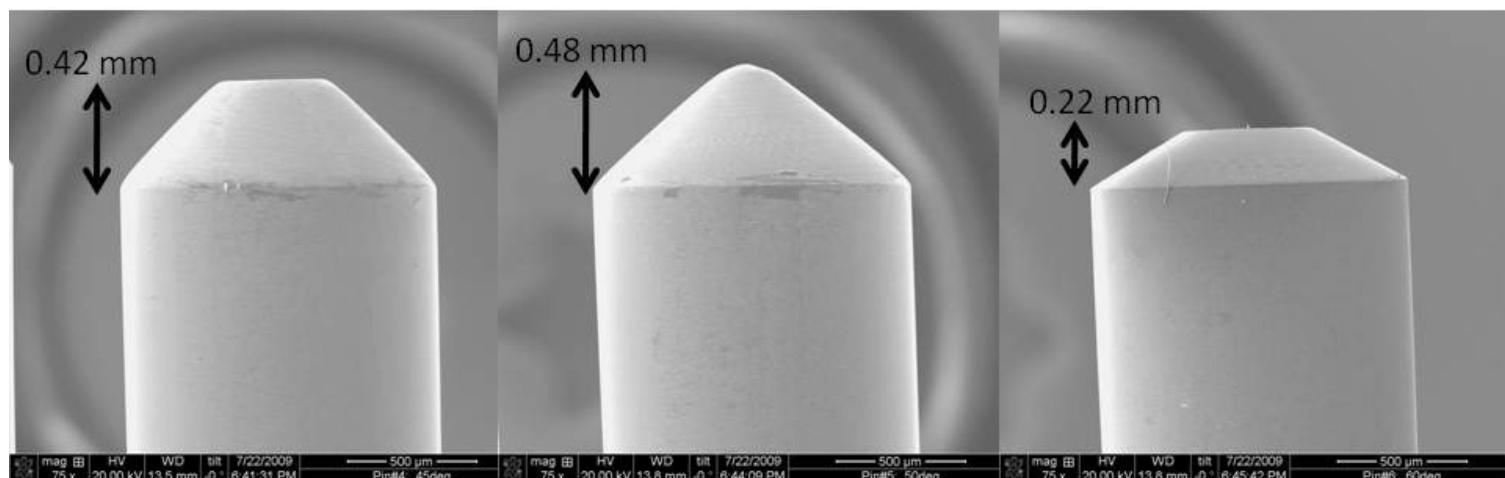
Effect of Chamfer Angle on Balseal Insertion Forces



#1: 20°

#2: 30°

#3: 40°



#4: 45°

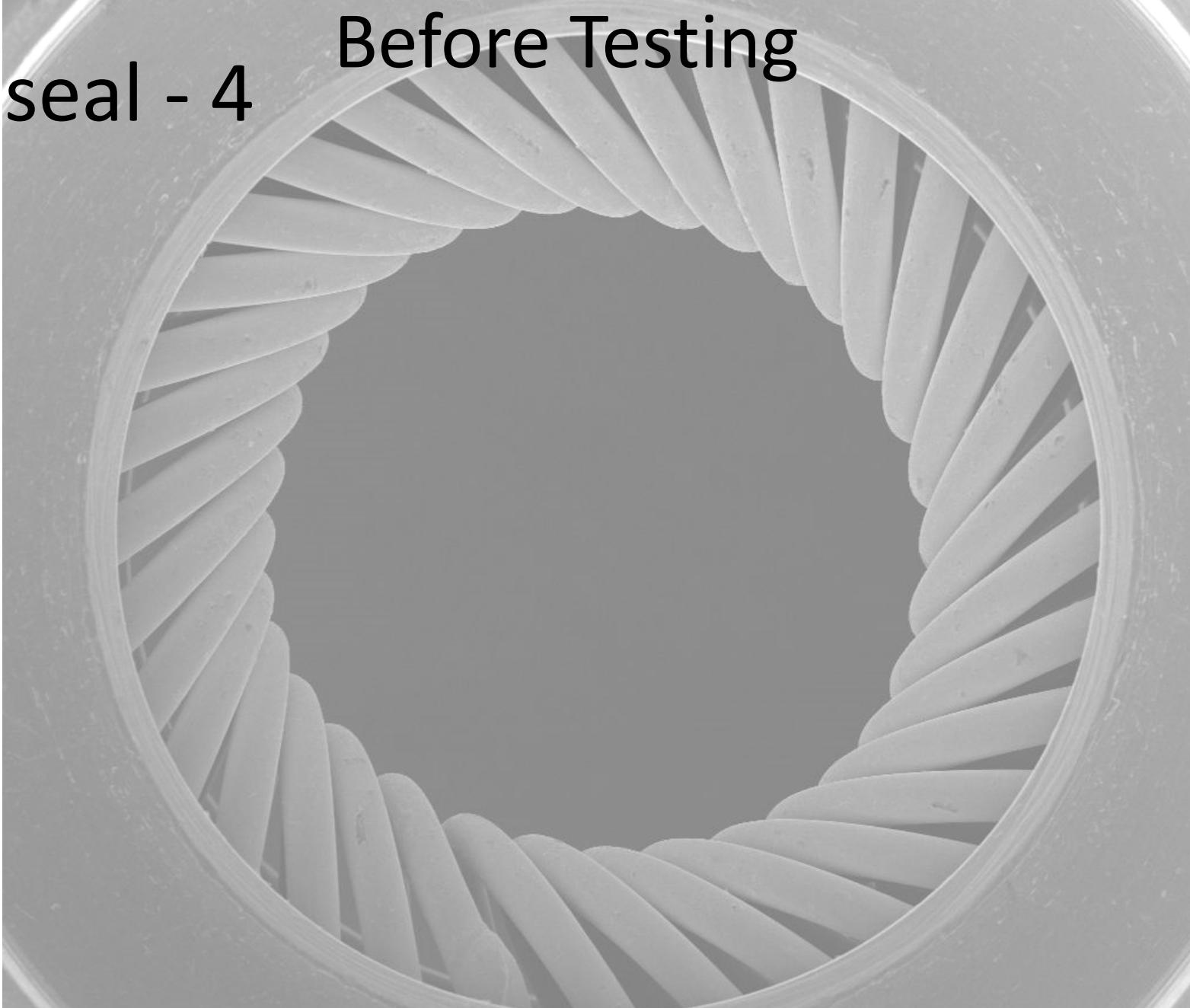
#5: 50°

#6: 60°

Chamfered ends of Gage Pins

Balseal - 4

Before Testing



mag
86 x

HV

20.00 kV

WD

23.0 mm

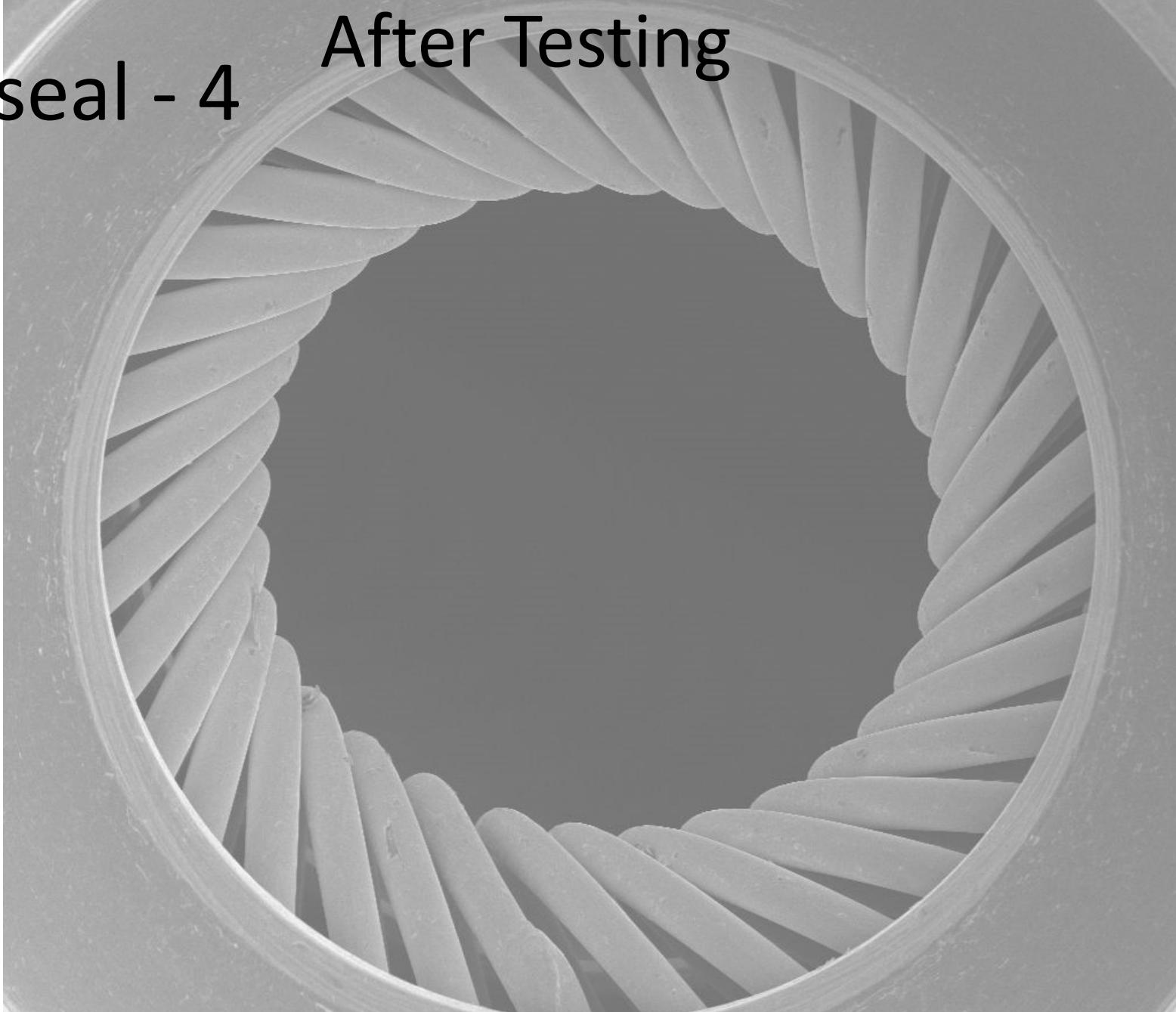
tilt

-0 °

7/22/2009
5:36:47 PM

500 µm
Balseal-4_Before Testing

Balseal - 4 After Testing



mag 田
88 x

HV
20.00 kV

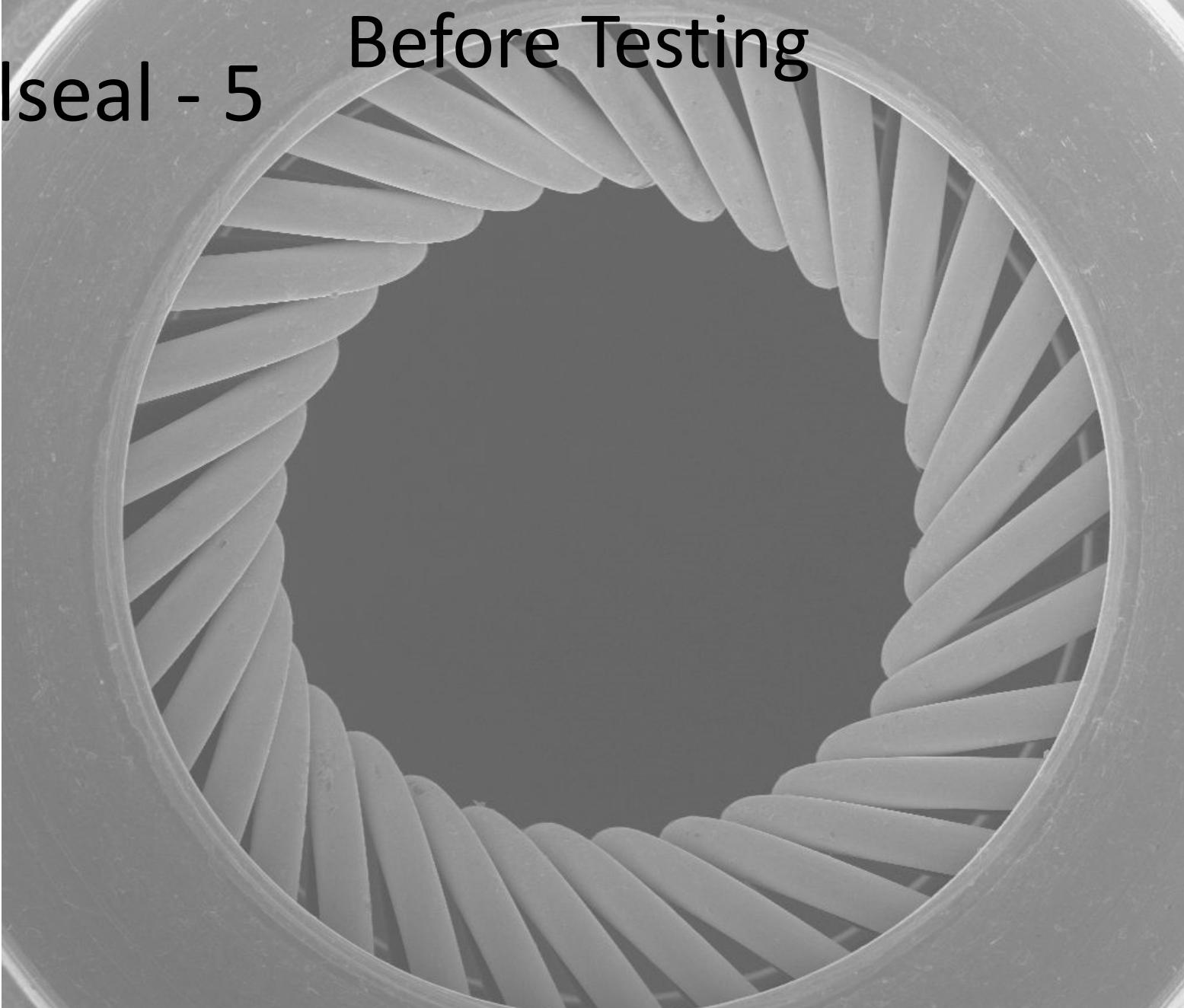
WD
23.0 mm

7/29/2009
5:18:27 PM

500 µm
Balseal-4 After Testing

Balseal - 5

Before Testing



mag
87 x

HV
20.00 kV

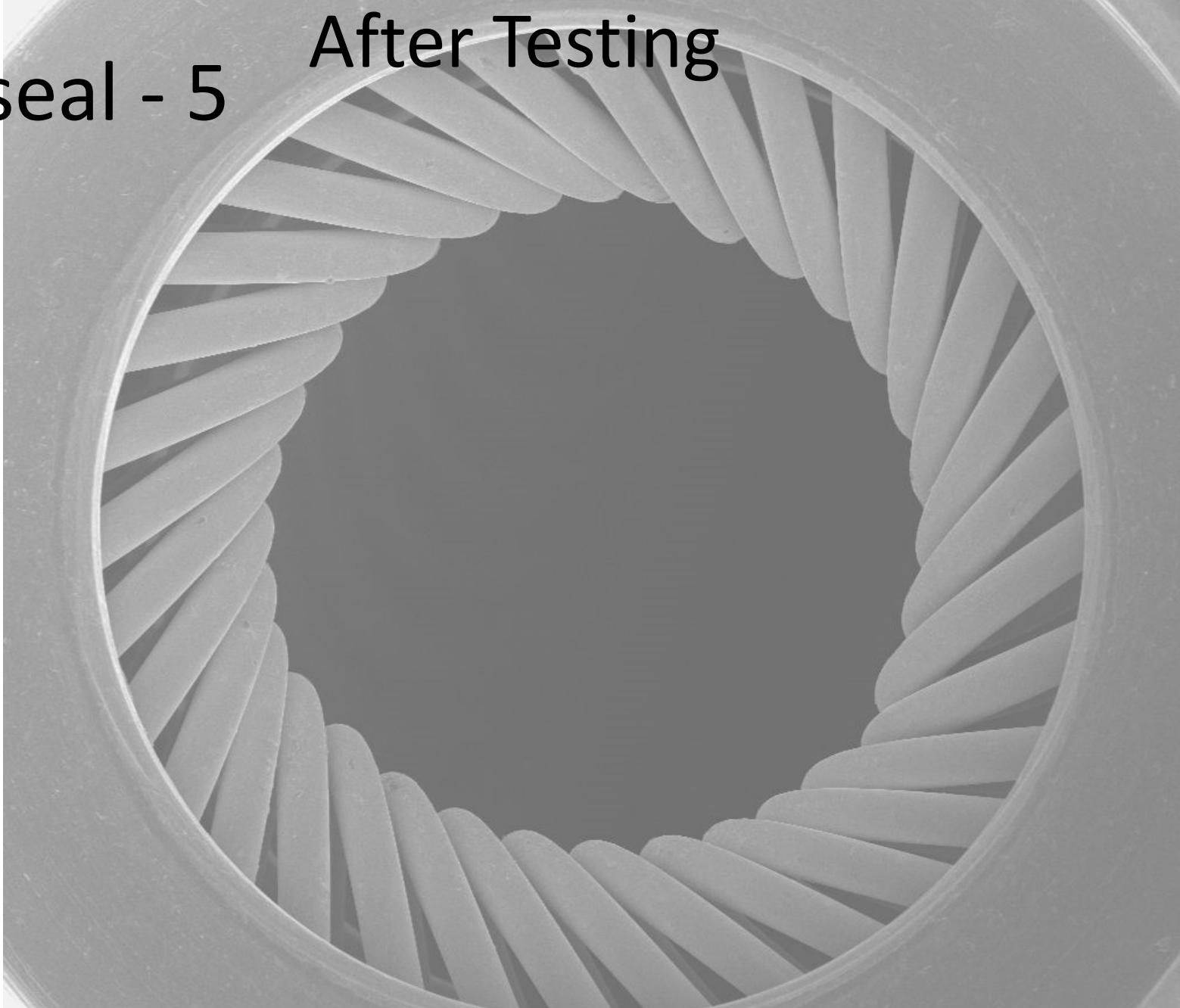
WD
22.7 mm

tilt
-0 °

7/22/2009
5:43:19 PM

500 µm
Balseal-5 Before Testing

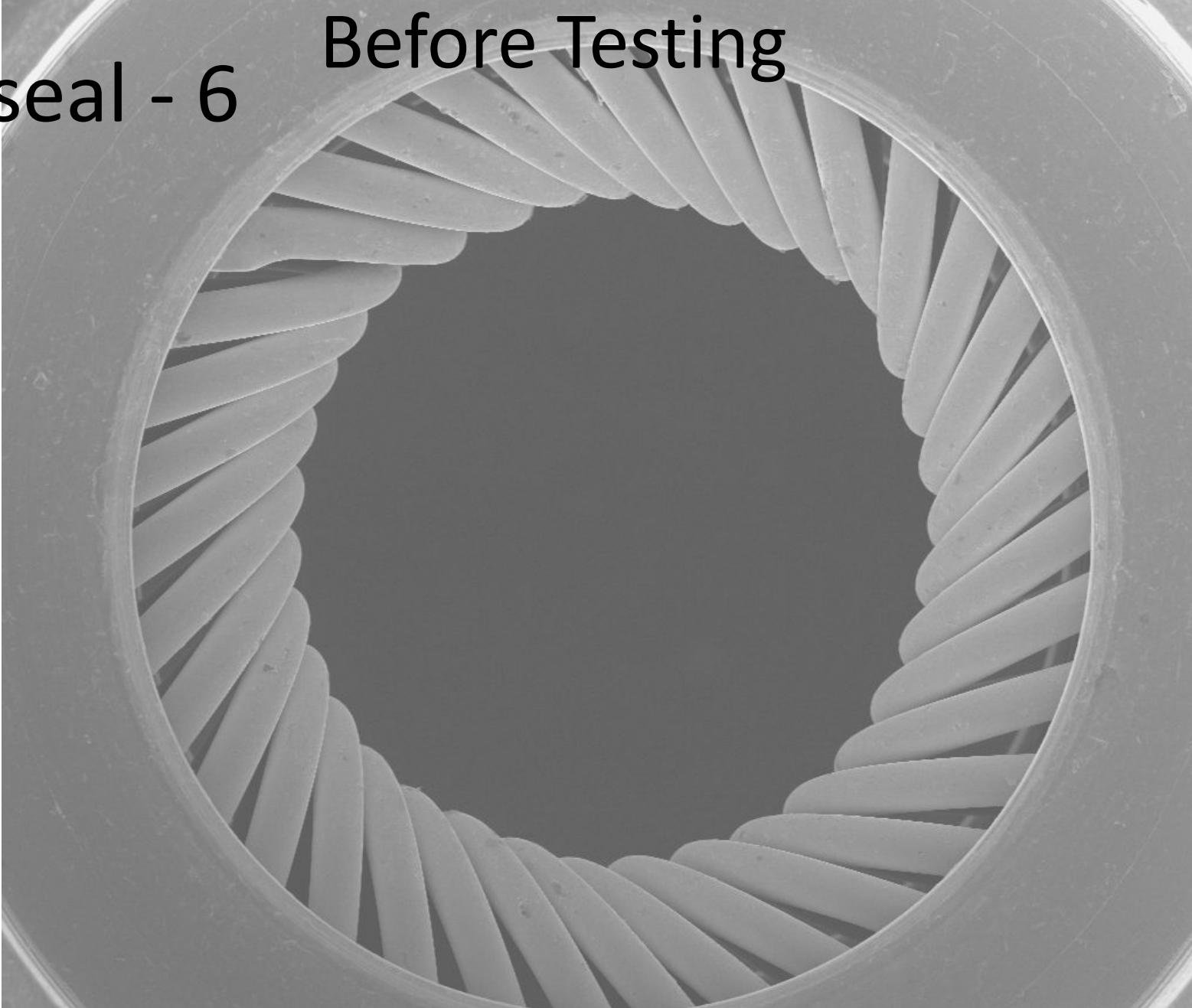
Balseal - 5 After Testing



mag 88 x HV 20.00 kV WD 23.0 mm 7/29/2009 5:20:56 PM 500 µm
Balseal-5 After Testing

Balseal - 6

Before Testing



mag
85 x

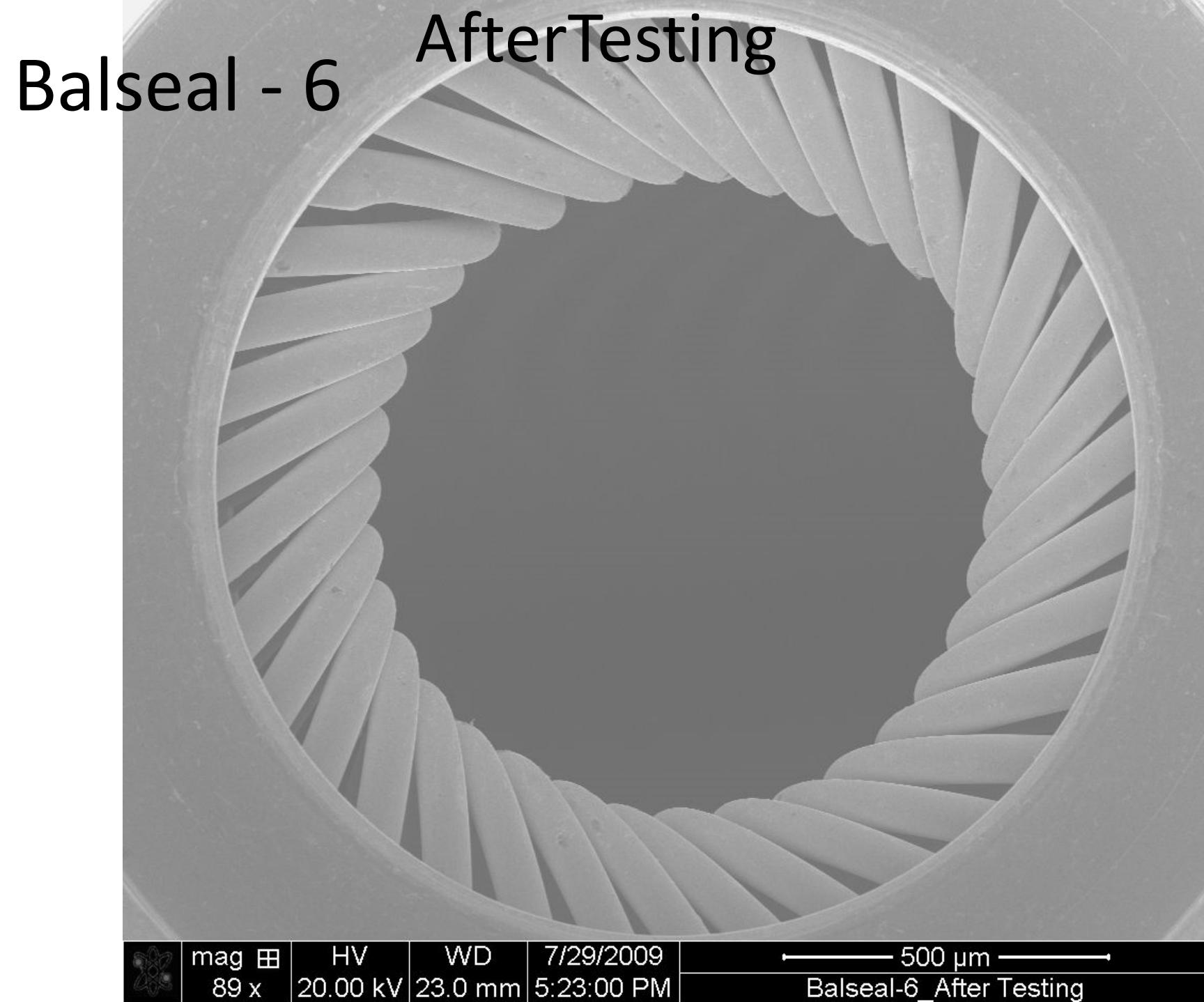
HV
20.00 kV

WD
22.8 mm

tilt
-0 °

7/22/2009
5:47:10 PM

500 µm
Balseal-6_Before Testing



Balseal - 6 AfterTesting



mag
89 x

HV
20.00 kV

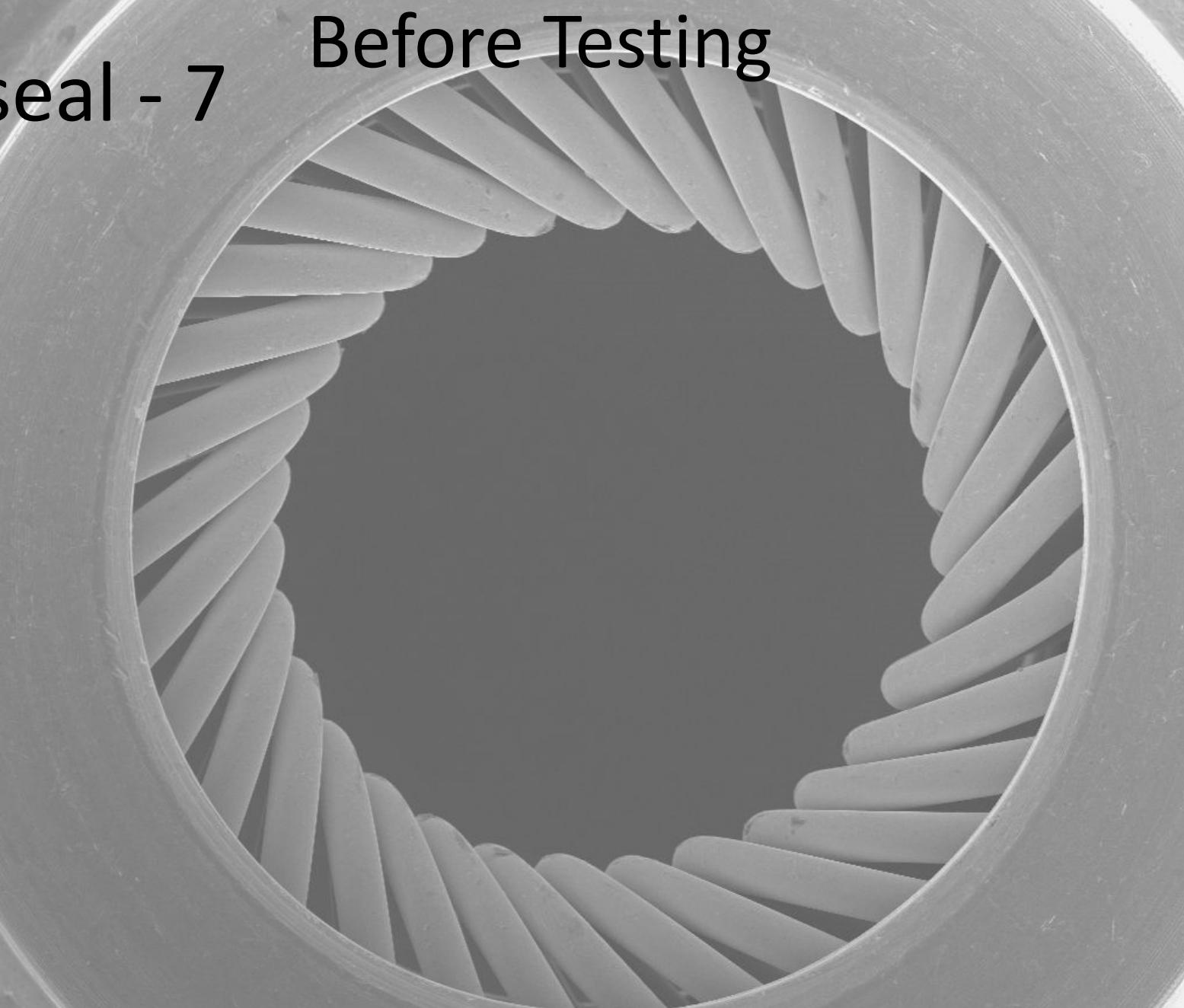
WD
23.0 mm

7/29/2009
5:23:00 PM

500 µm
Balseal-6 After Testing

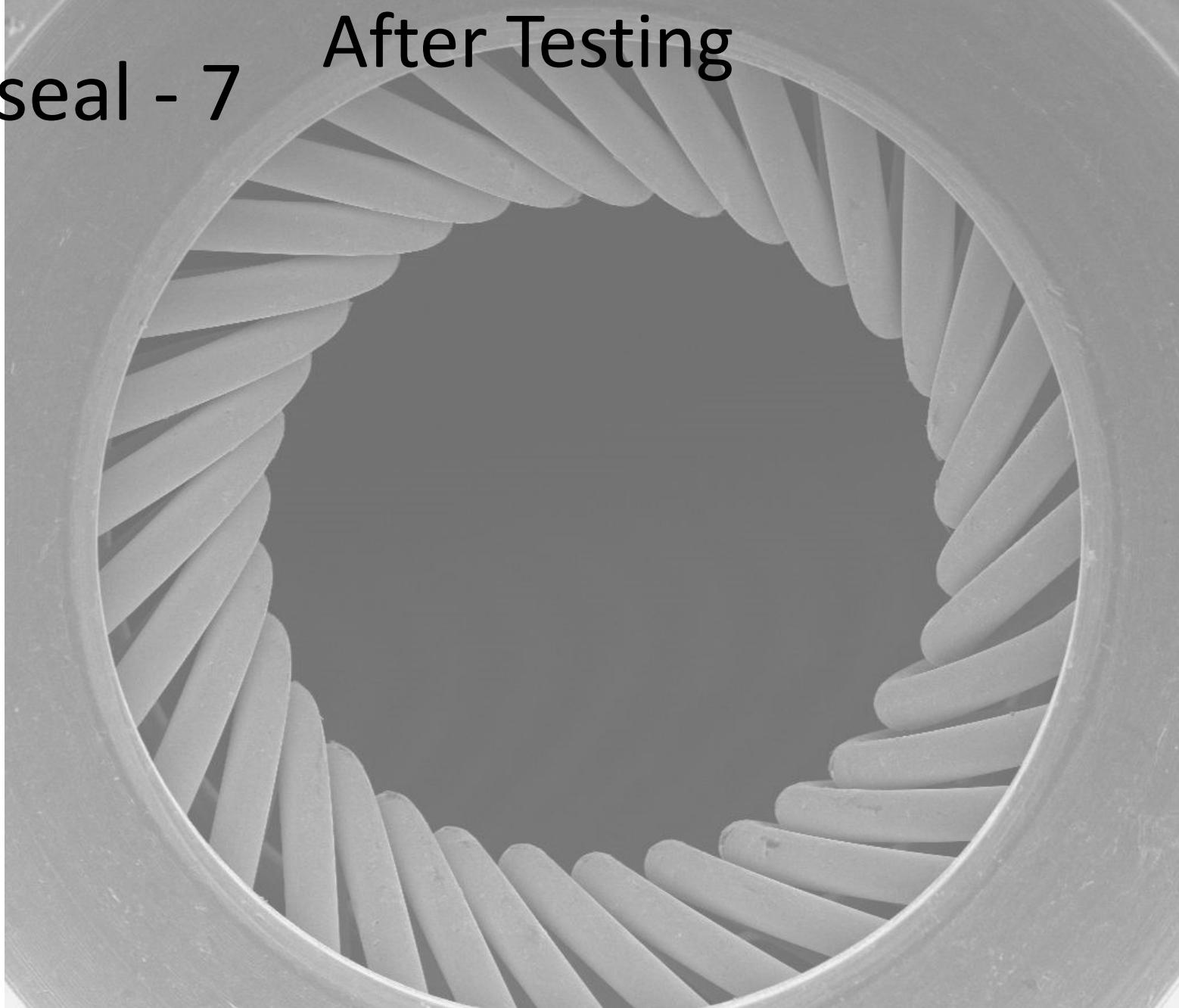
Balseal - 7

Before Testing



	mag 田	HV	WD	tilt	7/22/2009	500 µm
	85 x	20.00 kV	22.8 mm	-0 °	5:50:10 PM	Balseal-7_Before Testing

Balseal - 7 After Testing



mag
88 x

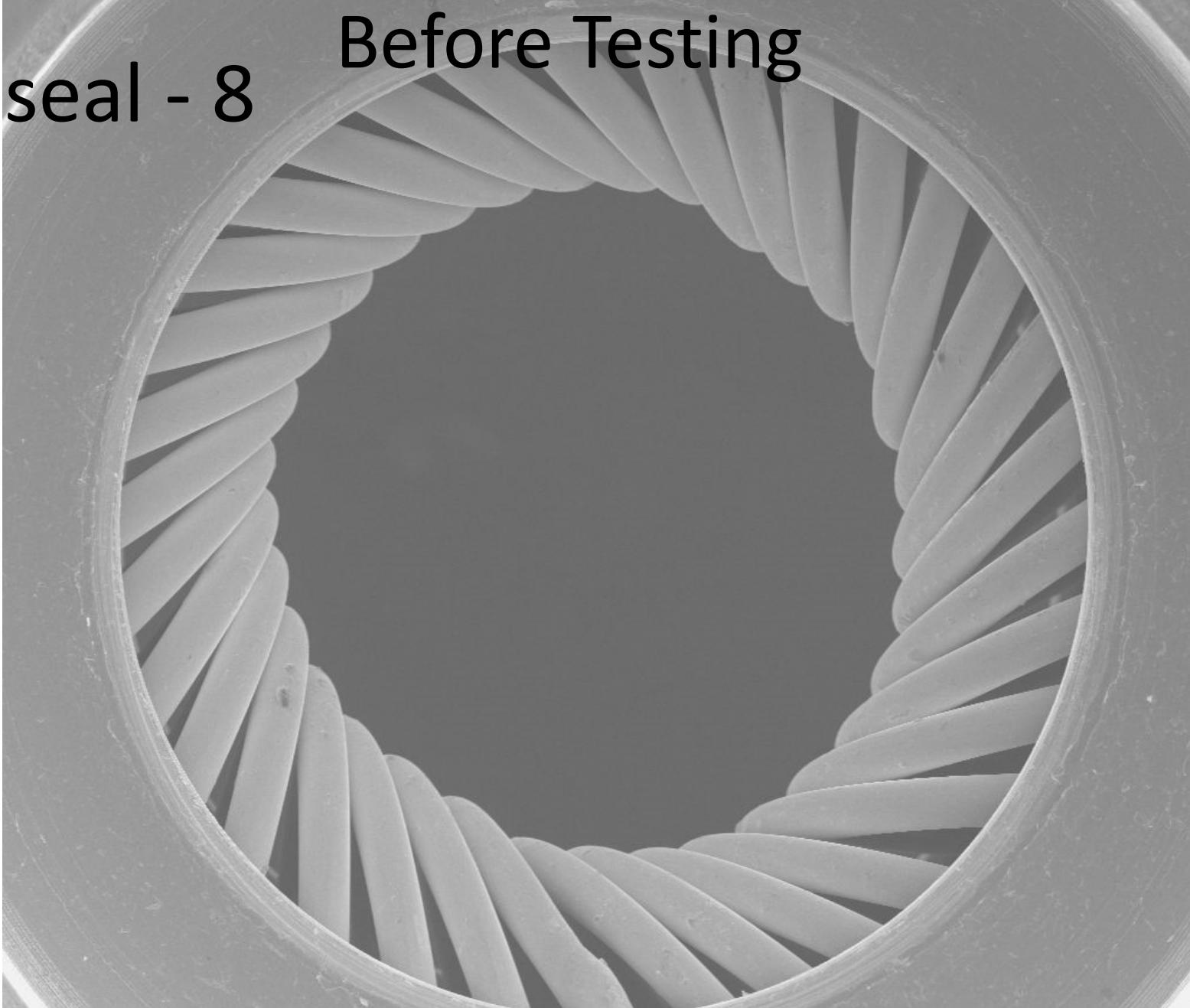
HV
20.00 kV

WD
23.0 mm

7/29/2009
5:25:19 PM

500 µm
Balseal-7 After Testing

Balseal - 8 Before Testing



mag 田
86 x

HV
20.00 kV

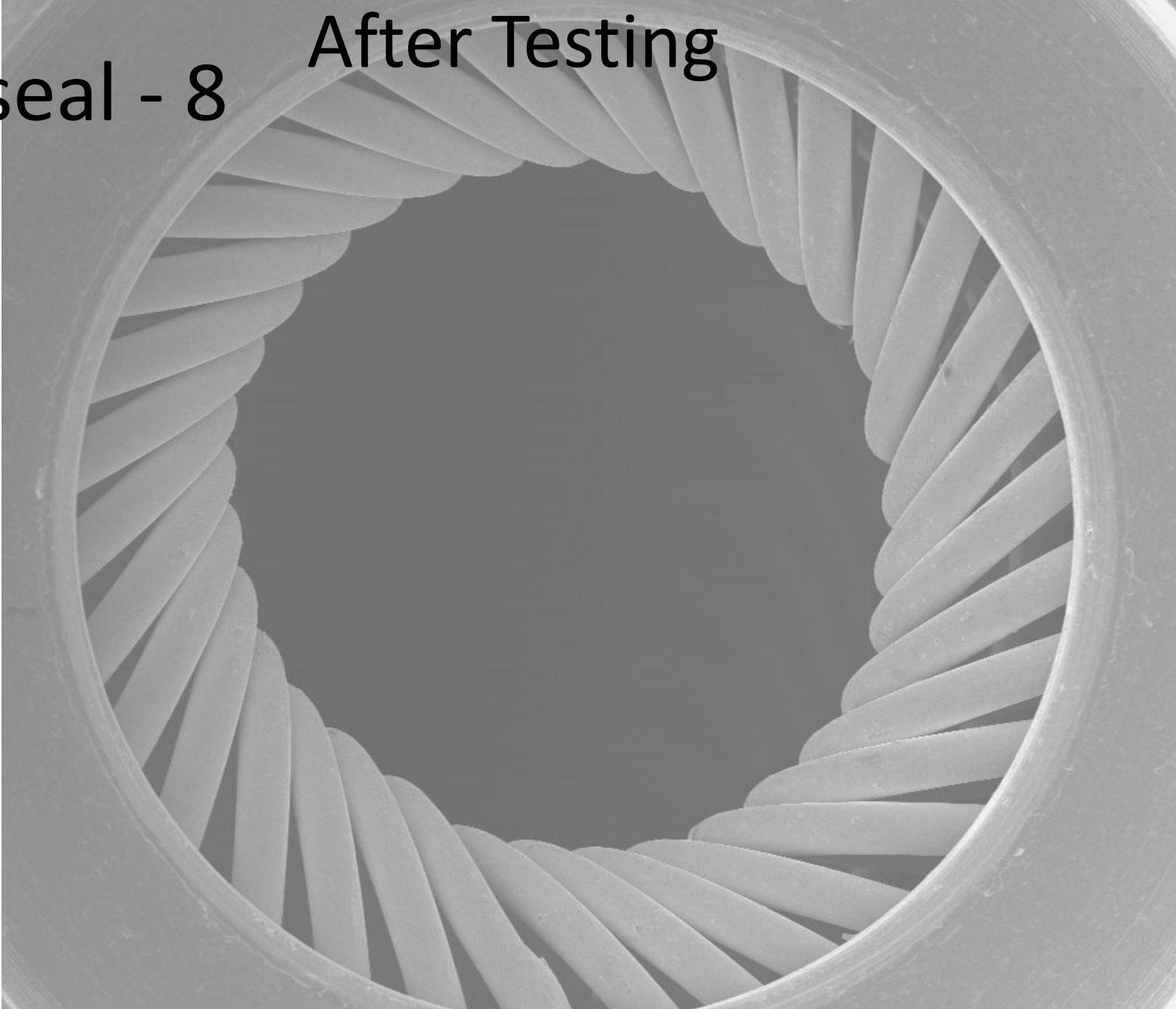
WD
22.4 mm

tilt
-0 °

7/22/2009
6:03:51 PM

— 500 µm —
Balseal-8_Before Testing

Balseal - 8 After Testing



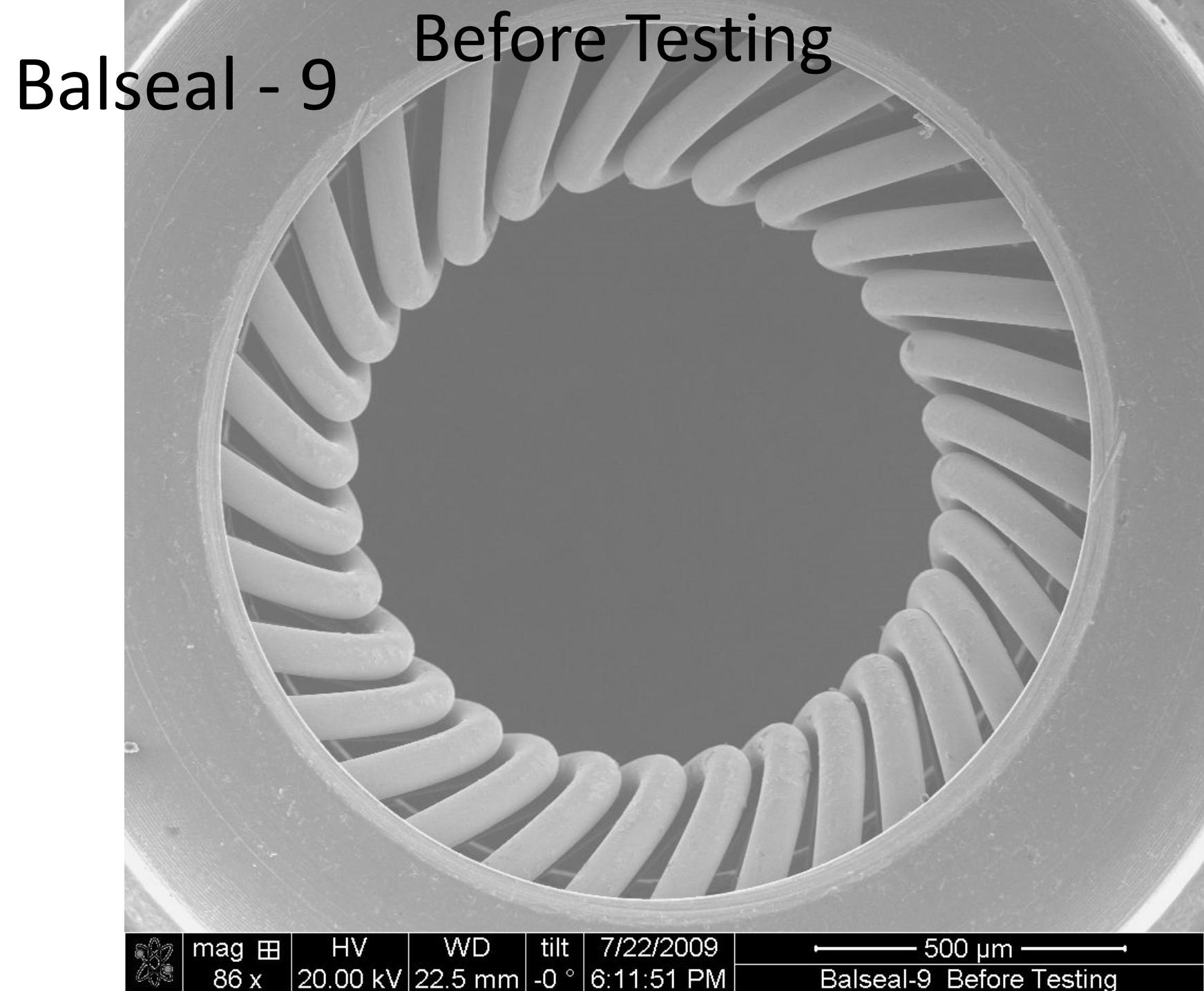
mag 田
89 x

HV
20.00 kV

WD
23.1 mm

7/29/2009
5:28:16 PM

500 µm
Balseal-8 After Testing



Balseal - 9 Before Testing



mag
86 x

HV
20.00 kV

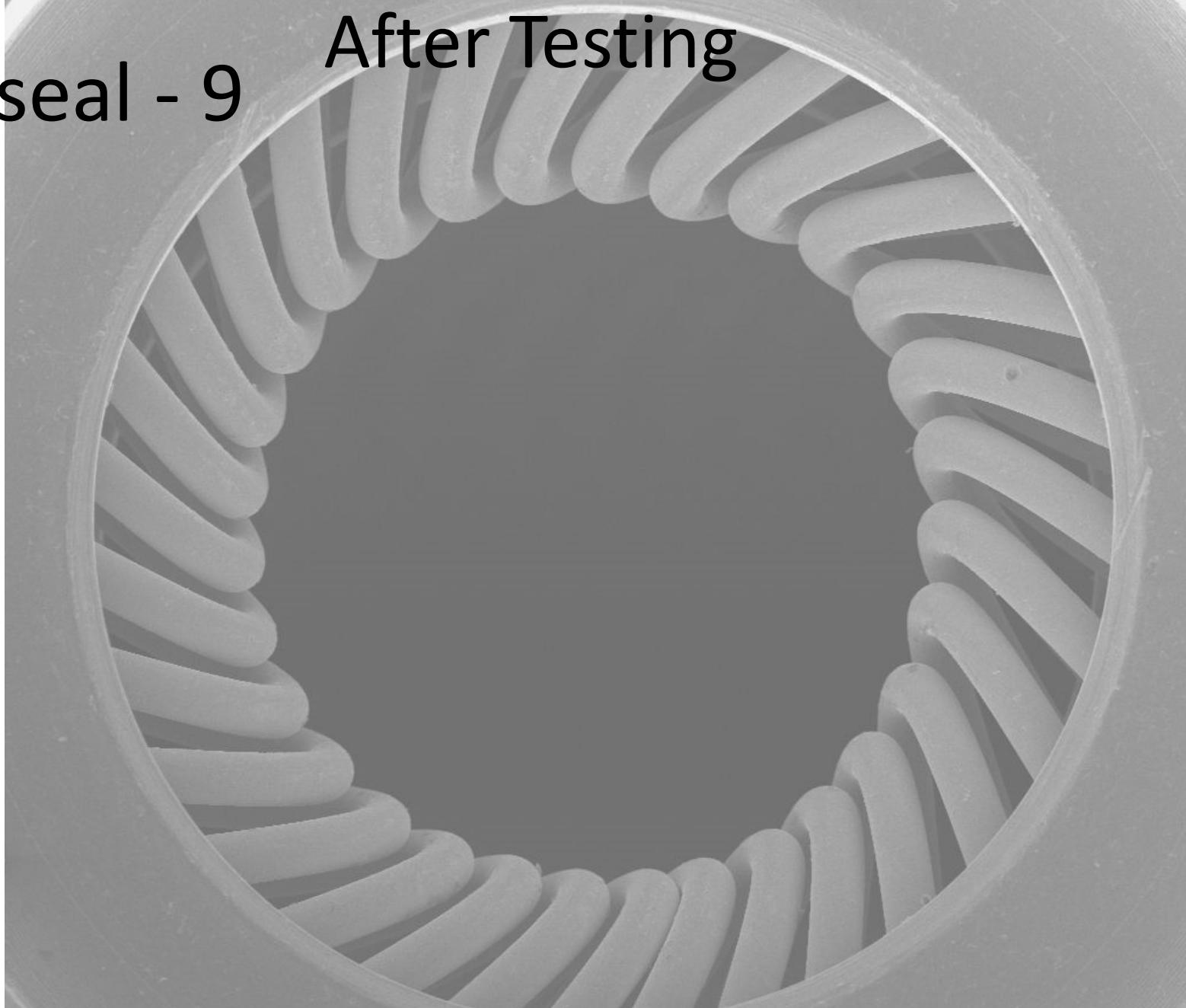
WD
22.5 mm

tilt
-0 °

7/22/2009
6:11:51 PM

500 µm
Balseal-9_Before Testing

Balseal - 9 After Testing



mag
90 x

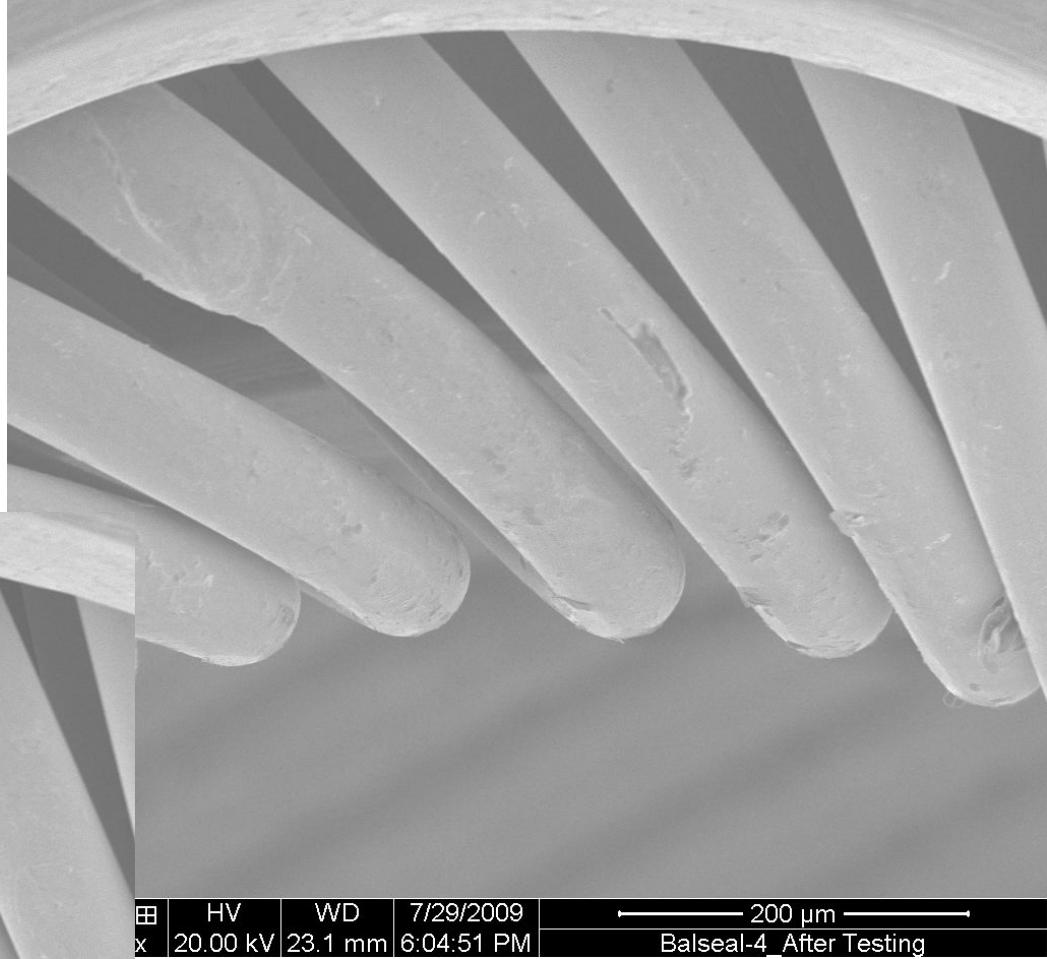
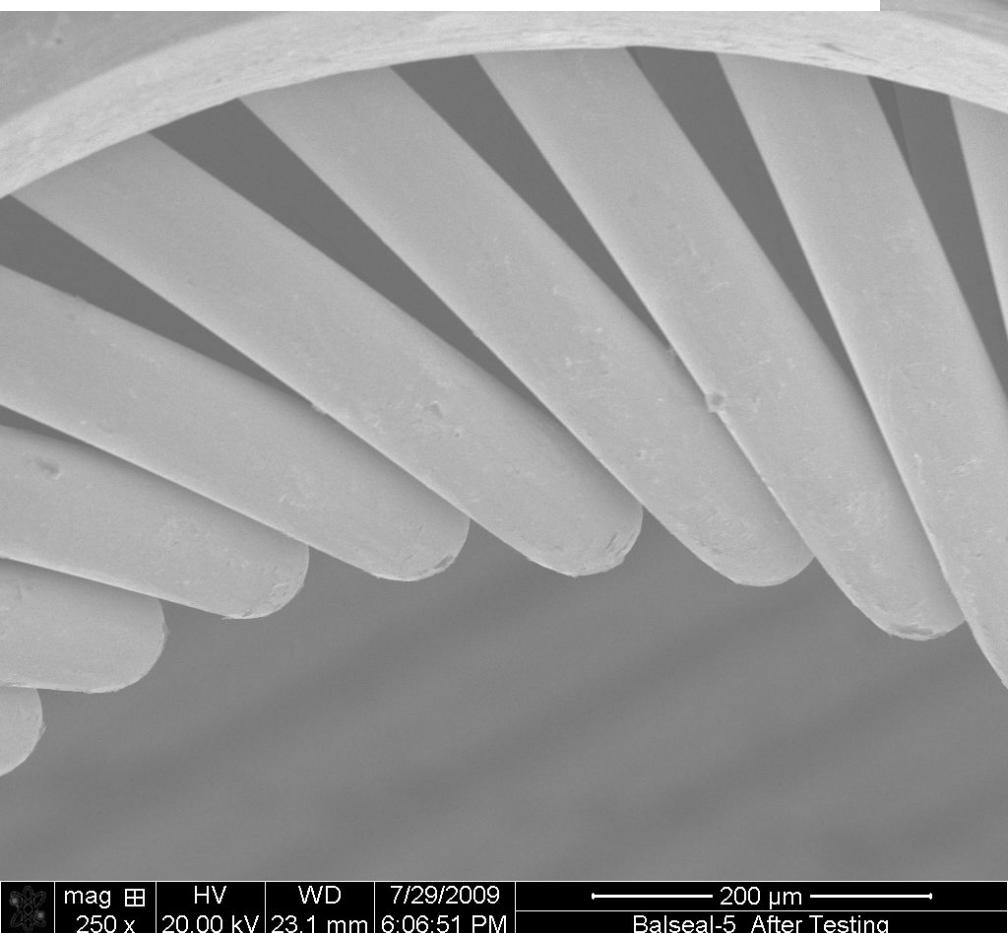
HV
20.00 kV

WD
23.1 mm

7/29/2009
5:30:48 PM

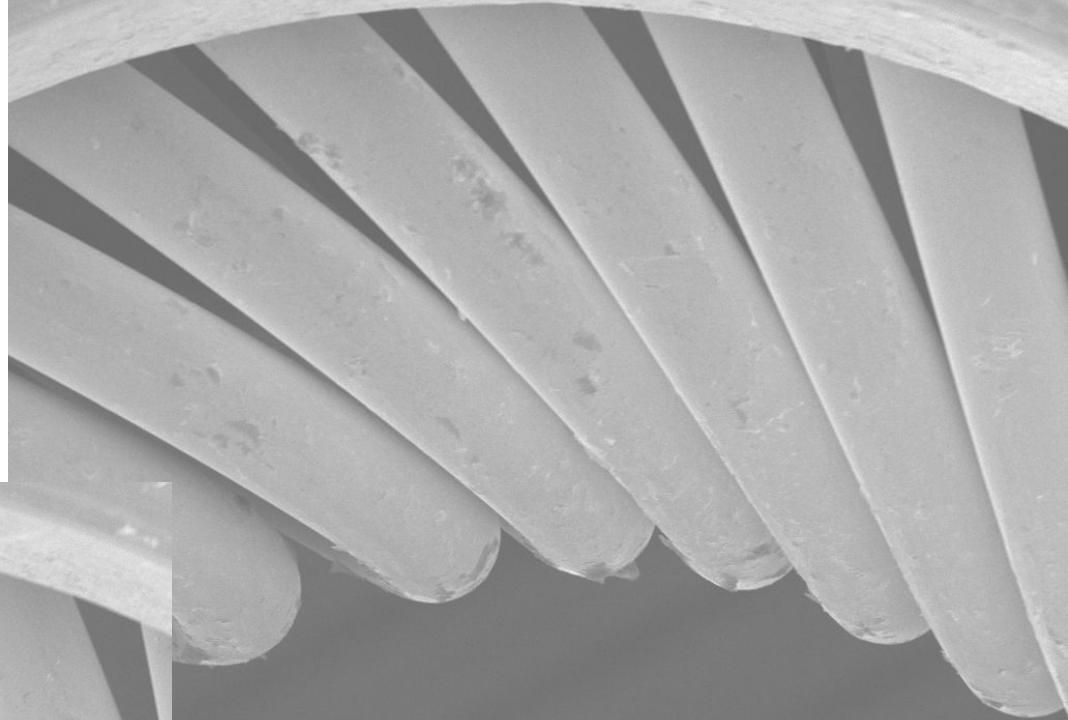
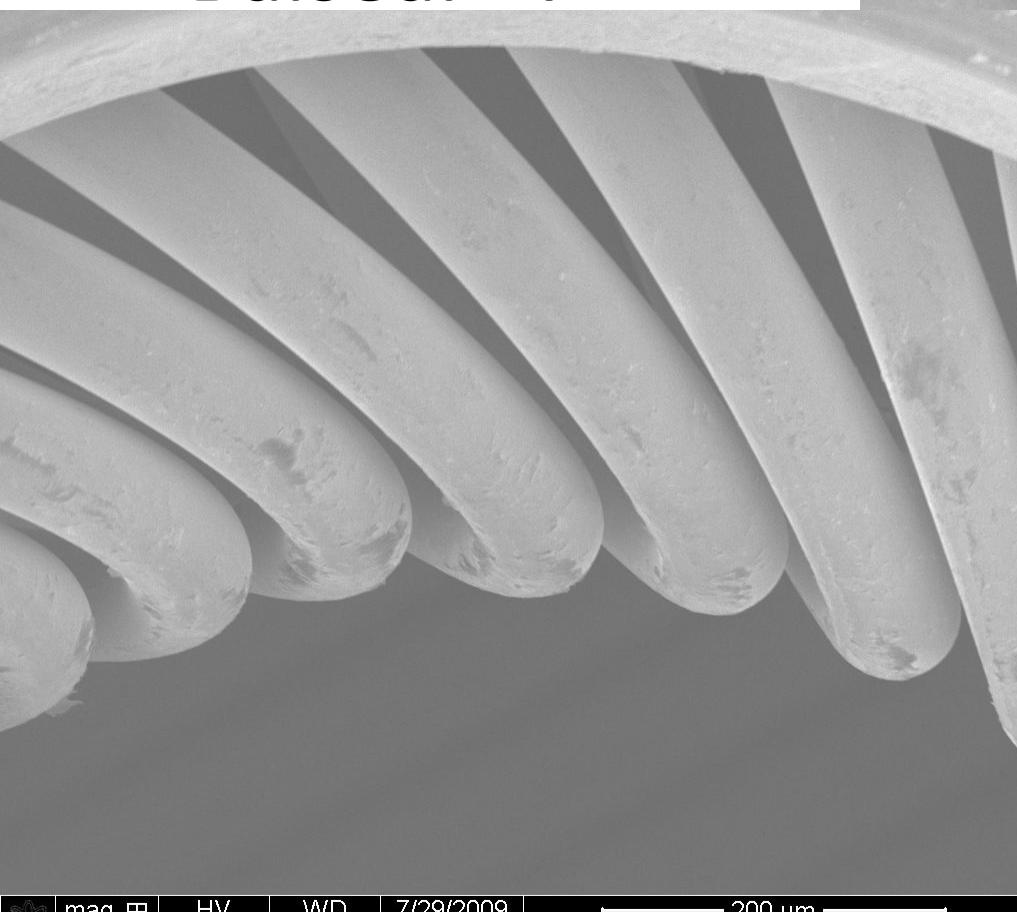
500 µm
Balseal-8 After Testing

After testing Balseal - 5



After testing Balseal - 4

After testing Balseal - 7

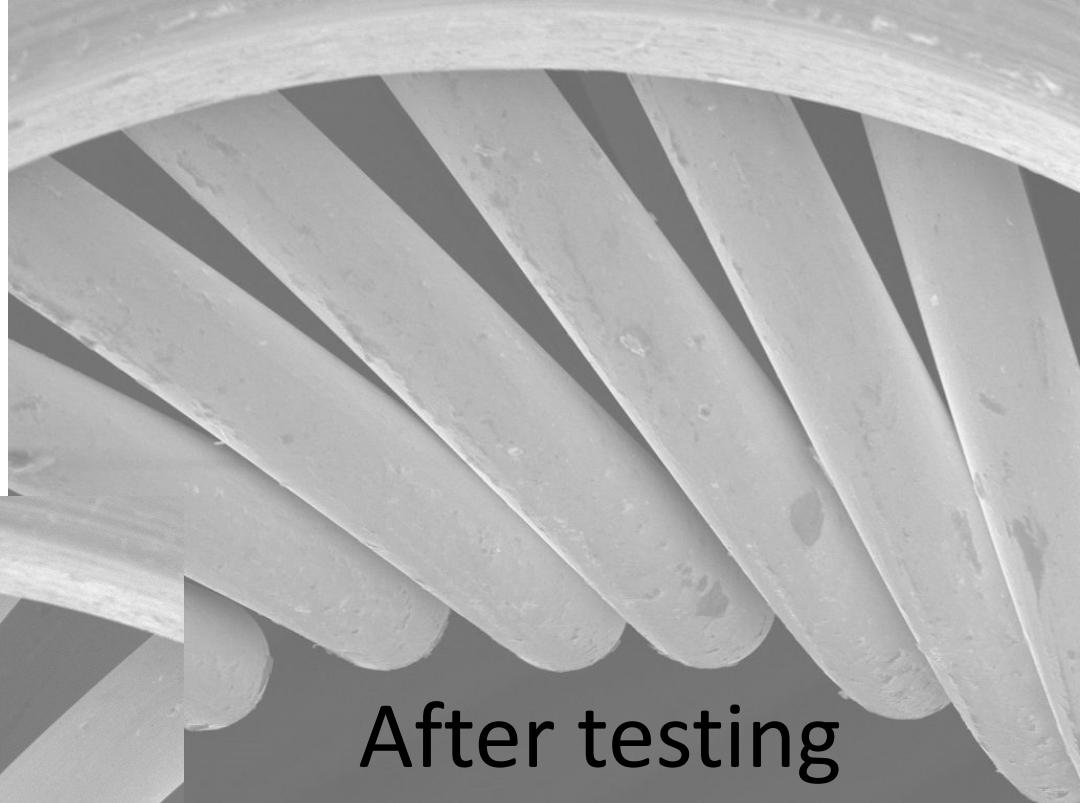


HV 20.00 kV WD 23.2 mm 7/29/2009 6:09:01 PM 200 µm Balseal-6 After Testing

After testing Balseal - 6

mag 250 x HV 20.00 kV WD 23.2 mm 7/29/2009 6:11:44 PM 200 µm Balseal-7 After Testing

After testing
Balseal - 9



After testing
Balseal - 8

HV | WD | 7/29/2009 | 200 µm
20.00 kV | 23.1 mm | 6:14:10 PM | Balseal-8 After Testing

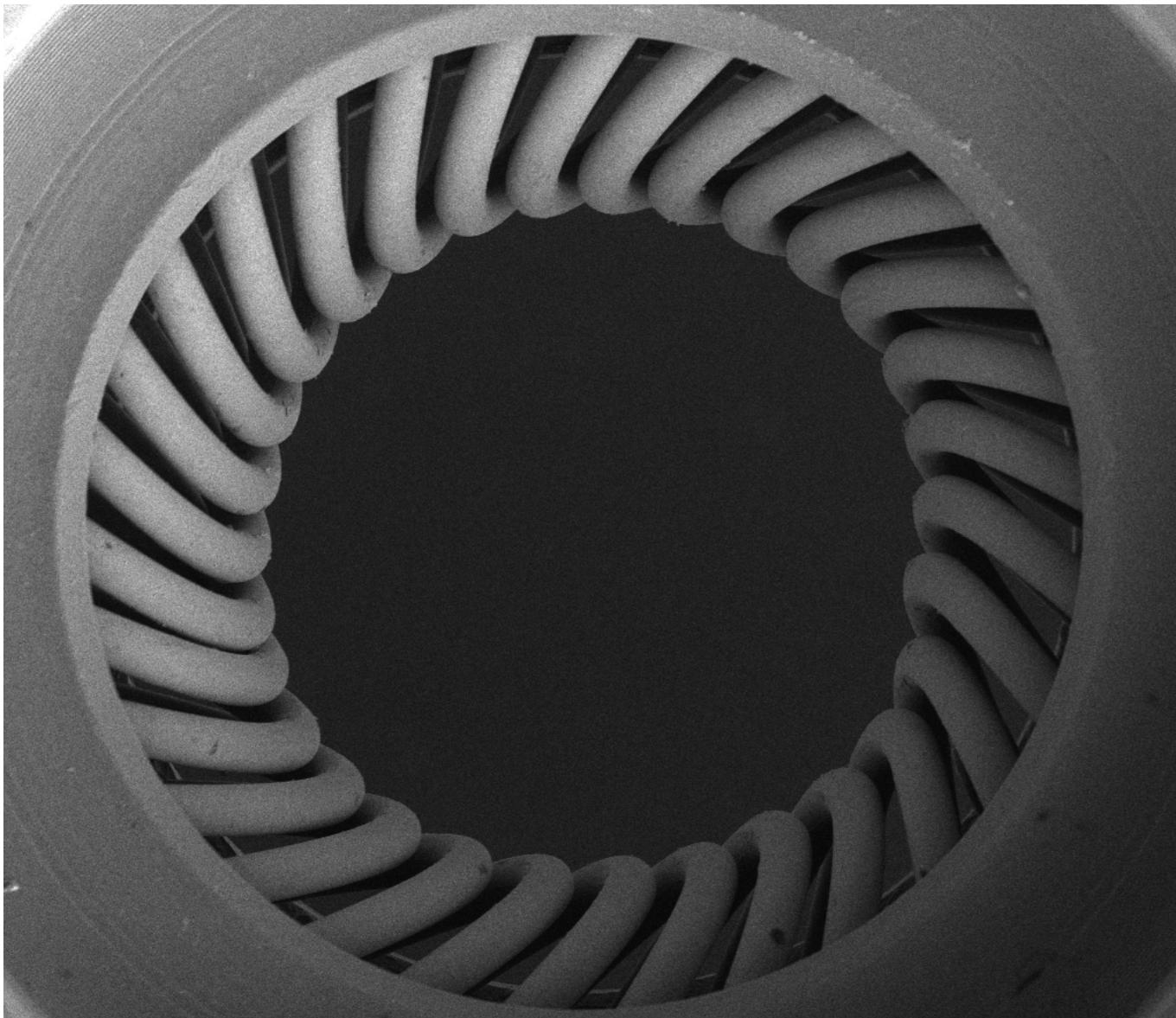
Conclusion:

No significant wear or damage
of the Balseal Springs up to a
chamfer angle of 60°



mag 田 HV WD 7/29/2009 | 200 µm
250 x 20.00 kV 23.3 mm 6:16:59 PM | Balseal-9 After Testing

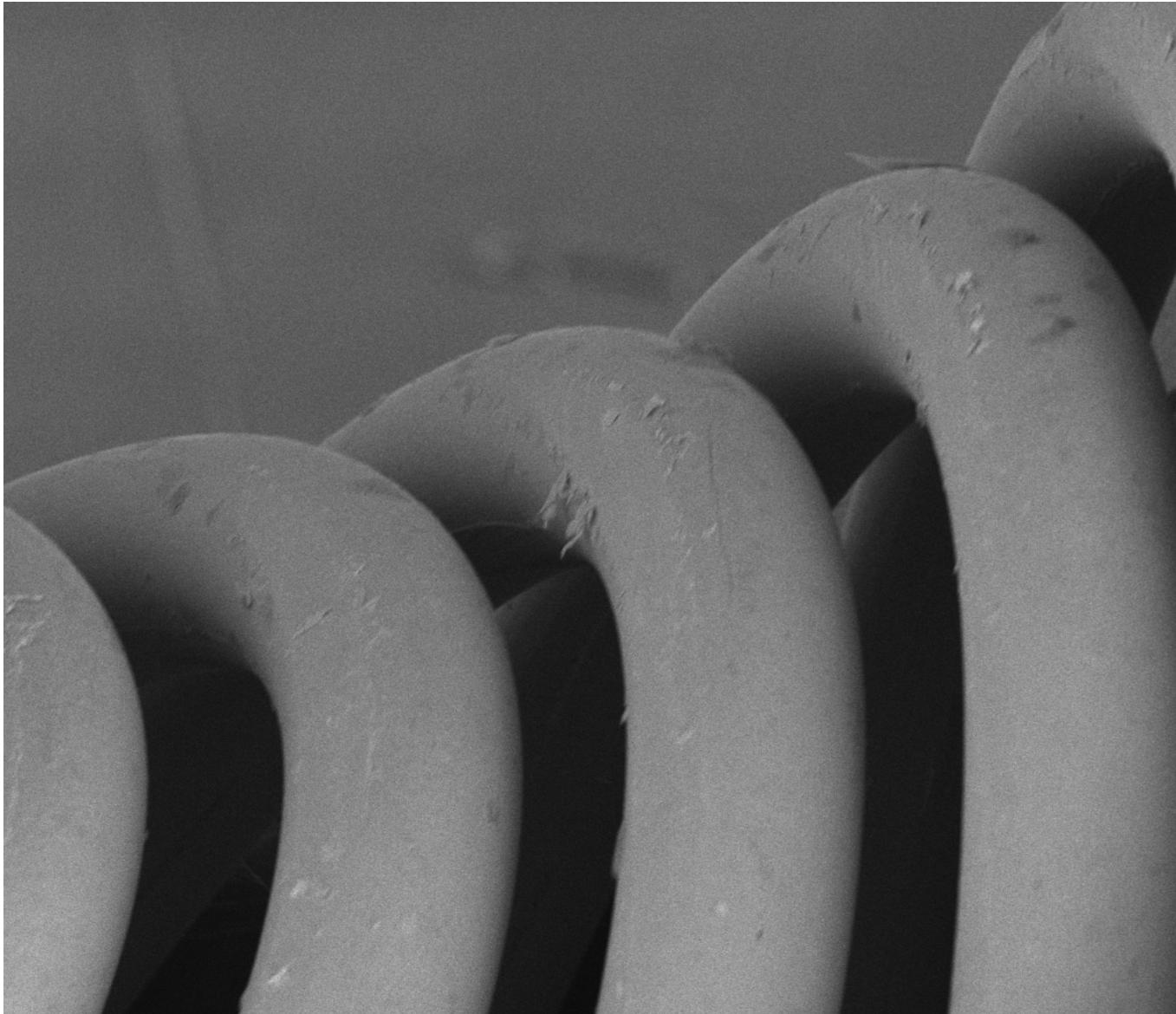
Balseal – 9: After 20 insertions of 60deg chamfer pin



ID Before Testing:
35.4 mil
ID After Testing:
36.6 mil

6/19/2009 | mag 87 x | HV 20.00 kV | WD 23.0 mm | 8/17/2009 | det ETD |  500 μm | Balseal-9 After inserting 60deg pin 20 t

Balseal – 9: After 20 insertions of 60deg chamfer pin



6/19/2024 | mag 400 x | HV 20.00 kV | WD 23.5 mm | 8/17/2009 2:06:40 PM | det ETD | 100 µm | Balseal-9 After inserting 60deg pin 20 t



Appendix 4

Balseal #	Spring ID (mil)	No of coils
11	36.9	39
13	37.9	39
17	38.2	39
18	38.2	39
20	38.9	39
15	38.1	40
19	38.9	40
6	35.0	35
4	36.0	33
7	36.0	31

Insertion force and Running force on 40 mil diameter pin with 20° chamfer

Balseal #	Spring ID (mil)	No of coils
6	35.0	35
4	36.0	33
7	36.0	31
12	37.0	39
17	38.0	39

Insertion force and Running force on 39 mil diameter pin with 20° chamfer