Reprocessing Of Single Use Screws A Study on the Effects of Repeated Reprocessing on Single-use Screws in Screw Caddies

Presented by:
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Declaration

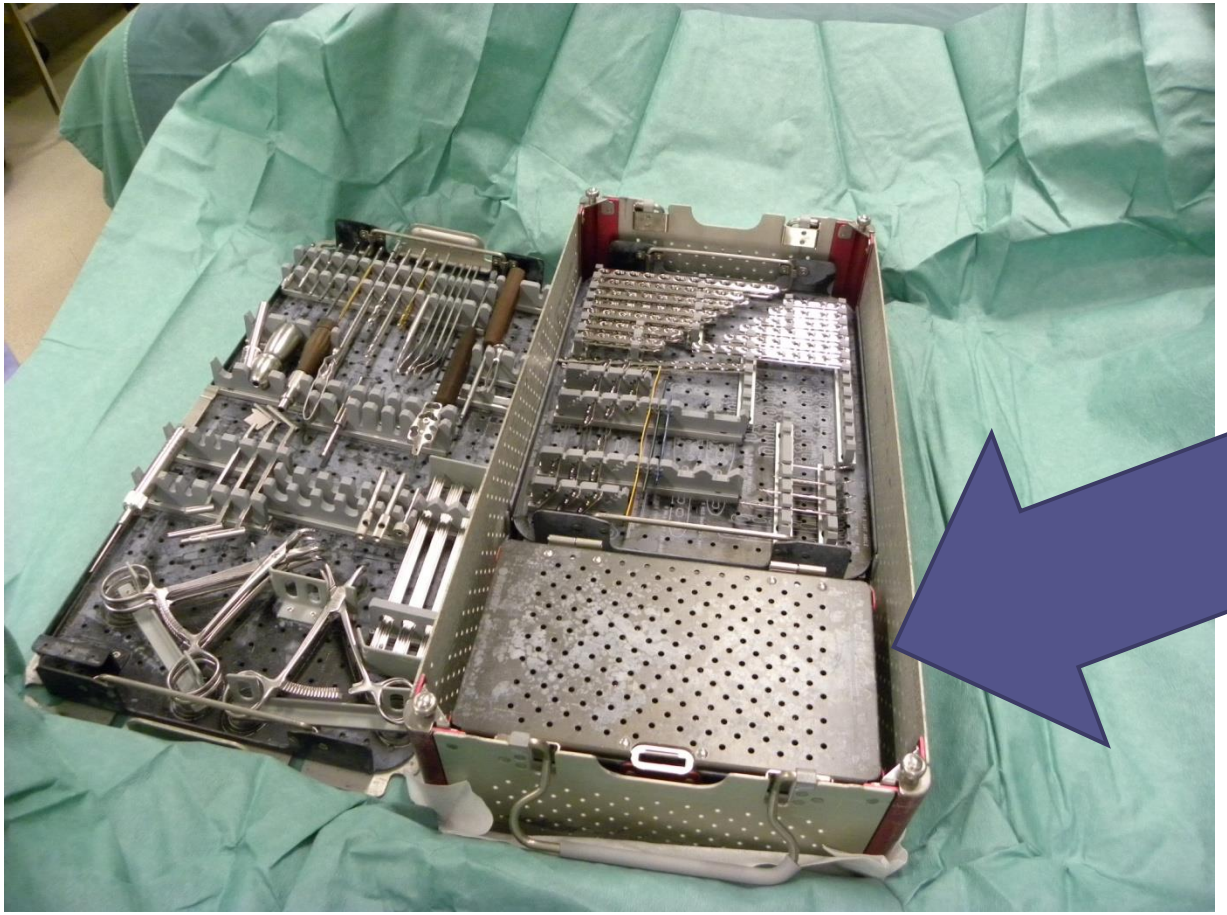
- Sponsorship to the amount of $1000.00 was received from SRACA Victoria. This money was used to purchase the implants used as controls and to replace those sampled from the small fragment sets.

- No conflicts to declare.

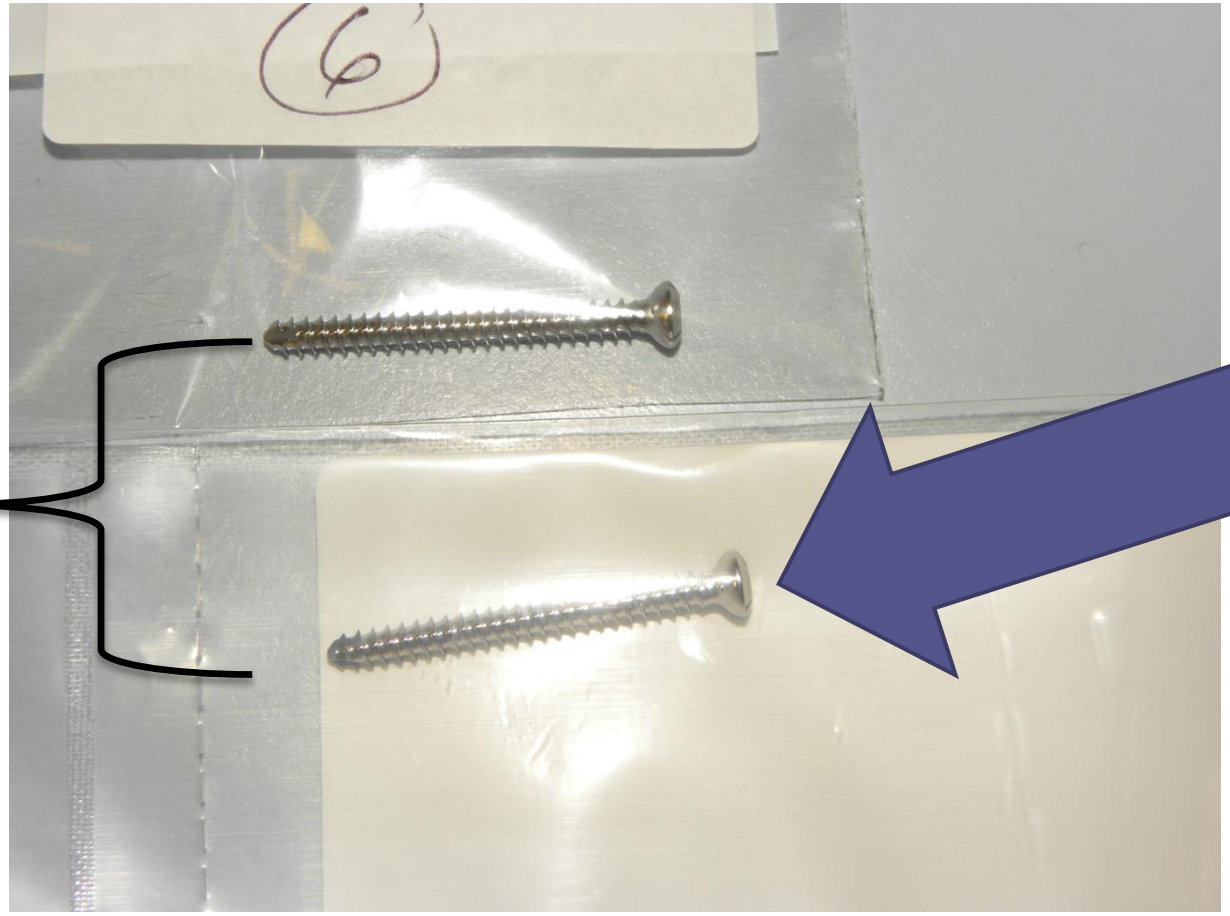
The experiment

- With cooperation of The Canberra Hospital
  - Randomly selected 2 small fragment sets from pool of 5 available
    - Small fragment sets reprocessed on average up to 600 times per annum
    - Processed through washer-disinfectors, packaged and steam sterilised
    - Sterile sets taken off shelf and opened aseptically to minimise risk of introduction of contaminants
    - All samples taken were replaced with brand new screws obtained direct from the manufacturer

Opened small fragment set



Bagged sample



Notice the colour difference?

Control screw

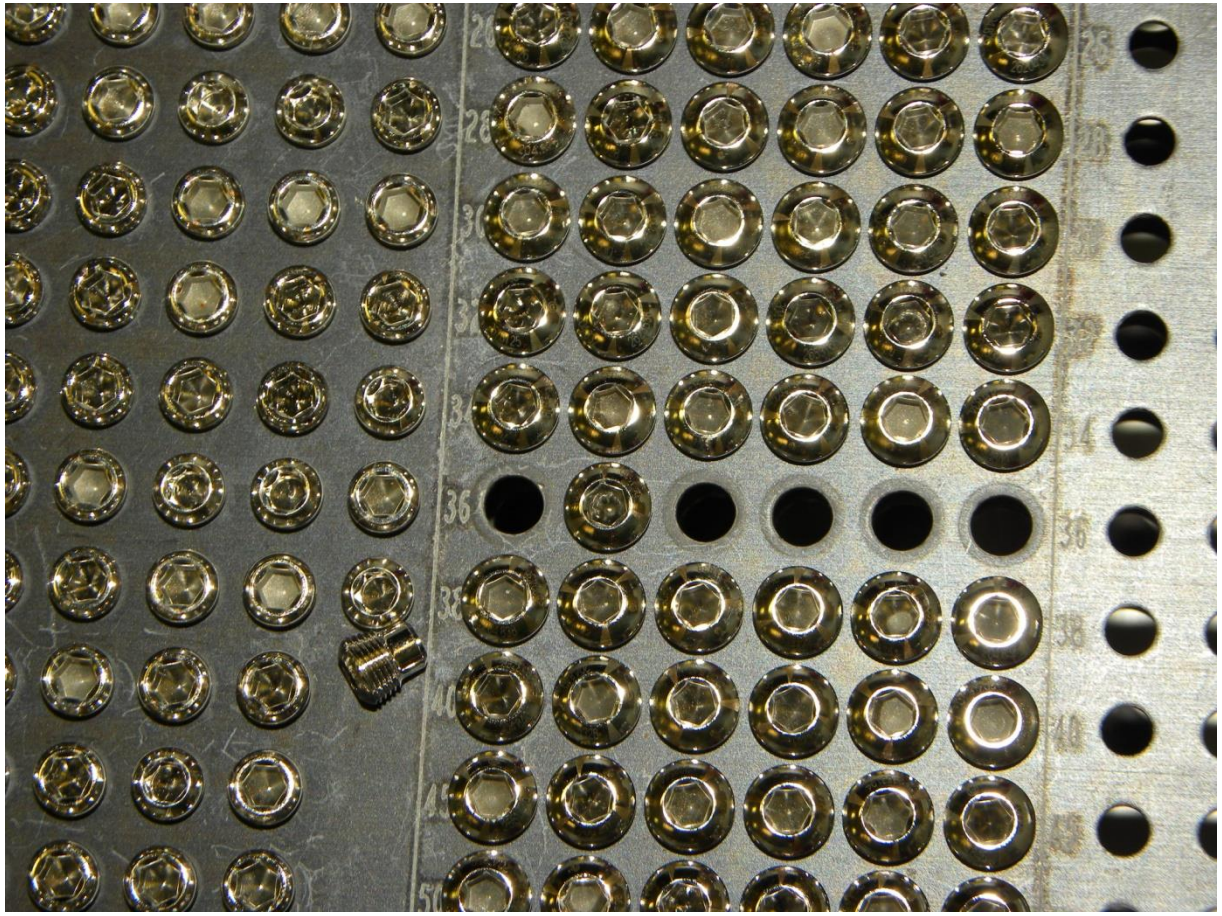
The Controls

Findings	Crystals	Debris	Fibres	Black sludge	Fibre -like	Film -like	Scratch	Dents	Striations	Fretting	Pitting	Black specks	Red film	Total findings per screw
Control 1	x		x				x							3
Control 2	x						x	x						3
Control 3	x	x	x			x								4
Control 4	x					x	x						x	4
Control 5	x	x												2
Control 6	x	x												2
Control 7	x													1
Control 8	x													1
Control 9	x							x					x	3
Control 10	x													1
TOTAL [n=10]	10	3	2	0	0	2	3	2	0	0	0	0	2	24

The Samples

- The samples
  - 5 screws from each of three categories were sampled from each set [30 samples total]
    - High usage [16mm], moderate usage [24mm], low usage [36mm]*
    - *Determined from data provided by the Canberra Hospital and the supplier
    - Base Assumption: high usage screws will have been subject to the least number of reprocessing cycles, low usage screws will have been subjected to the most reprocessing cycles

After sampling 36mm screws



The samples

- All samples showed evidence of contaminants that were not observable on the control screws
- There did not appear to be any quantifiable difference in the rates of contamination of screws from Set A versus Set B

Reprocessed screws

Findings	Crystals	Debris	Fibres	Black sludge	Fibre -like	Film-like	Scratches	Dents	Striations	Fretting	Pitting	Black specks	Red film
High Usage 16mm Screws n=10 TOTAL	8	9	3	0	3	1	0	1	0	0	0	1	0
Moderate Usage 24mm screws n=10 TOTAL	1	9	8	5	7	2	0	2	3	2	0	4	3
Low Usage 36mm screws n=10 TOTAL	2	10	7	10	6	2	0	0	5	4	1	9	1
TOTAL [n=30]	11	28	18	15	16	5	0	3	8	6	1	14	4

Overall findings

Findings	Crystals	Debris	Fibres	Black sludge	Fibre -like	Film-like	Scratches	Dents	Striations	Fretting	Pitting	Black specks	Red film
Overall Total on Control Screws n=10	10	3	2	0	0	2	3	2	0	0	0	0	2
Overall Total on Reprocessed Screws n=30	11	28	18	15	16	5	0	3	8	6	1	14	4

Data analysis

- Data was analysed using
  - Mann-Whitney U test & Kruskall-Wallis test
    - Establishes if there were any significant differences between the samples
  - Correlation and simple linear regression analysis
    - Establishes whether any relationships existed between the number of exposures to reprocessing cycles and rates of observed contamination and corrosion, deterioration and damage and
  - ANOVA
    - a one tailed analysis of variance or test to establish that should the sample population exhibit normal distribution, the results obtained would continue to demonstrate a statistical difference

Mann-Whitney U test -contaminates

Baseline (U_1)	Comparison group (U_2)	U_1 = n1n2+n1(n1=1)/2-R1 U_2 = n1n2+n1(n1=1)/2-R2 U= lowest value	Critical value two-tail Mann-Whitney U test table Reject H_o if: U ≤ 23 p<0.05 U ≤ 16 p<0.01	Outcome There is no difference = Accept H_o There is a difference = Reject H_o
Control	High usage	U_1 =71.5 U_2 =29.5	29.5 > 23	Accept H_o
	Moderate usage	U_1 = 81 U_2 = 19	19 < 23	Reject H_o p< 0.05
	Low usage	U_1 = 92 U_2=8	8 < 16	Reject H_o p< 0.01
High usage	Moderate usage	U_1 = 67 U_2 = 33	33 > 23	Accept H_o
	Low usage	U_1 = 86 U_2 = 14	14 < 16	Reject H_o p< 0.01
Moderate usage	Low usage	U_1 = 59.5 U_2 = 40.5	40.5 > 23	Accept H_o

Mann-Whitney U test – corrosion etc

Baseline (U_1)	Comparison group (U_2)	U_1 = n1n2+n1(n1=1)/2-R1 U_2 = n1n2+n1(n1=1)/2-R2 U= lowest value	Critical value two-tail Mann-Whitney U test table Reject H_0 if: U ≤ 23 p<0.05 U ≤ 16 p<0.01	Outcome There is no difference = Accept H_0 There is a difference = Reject H_0
Control	High usage	U_1 =36 U_2 =64	36 > 23	Accept H_0
	Moderate usage	U_1 = 89 U_2 = 34	34 > 23	Accept H_0
	Low usage	U_1 = 88 U_2=12	12 < 16	Reject H_0 p< 0.01
High usage	Moderate usage	U_1 = 84 U_2 = 16	16 ≤ 16	Reject H_0 p< 0.01
	Low usage	U_1 = 97 U_2 = 3	3 < 16	Reject H_0 p< 0.01
Moderate usage	Low usage	U_1 = 77 U_2 = 23	23 ≤ 23	Reject H_0 p< 0.05

Kruskall-Wallis test

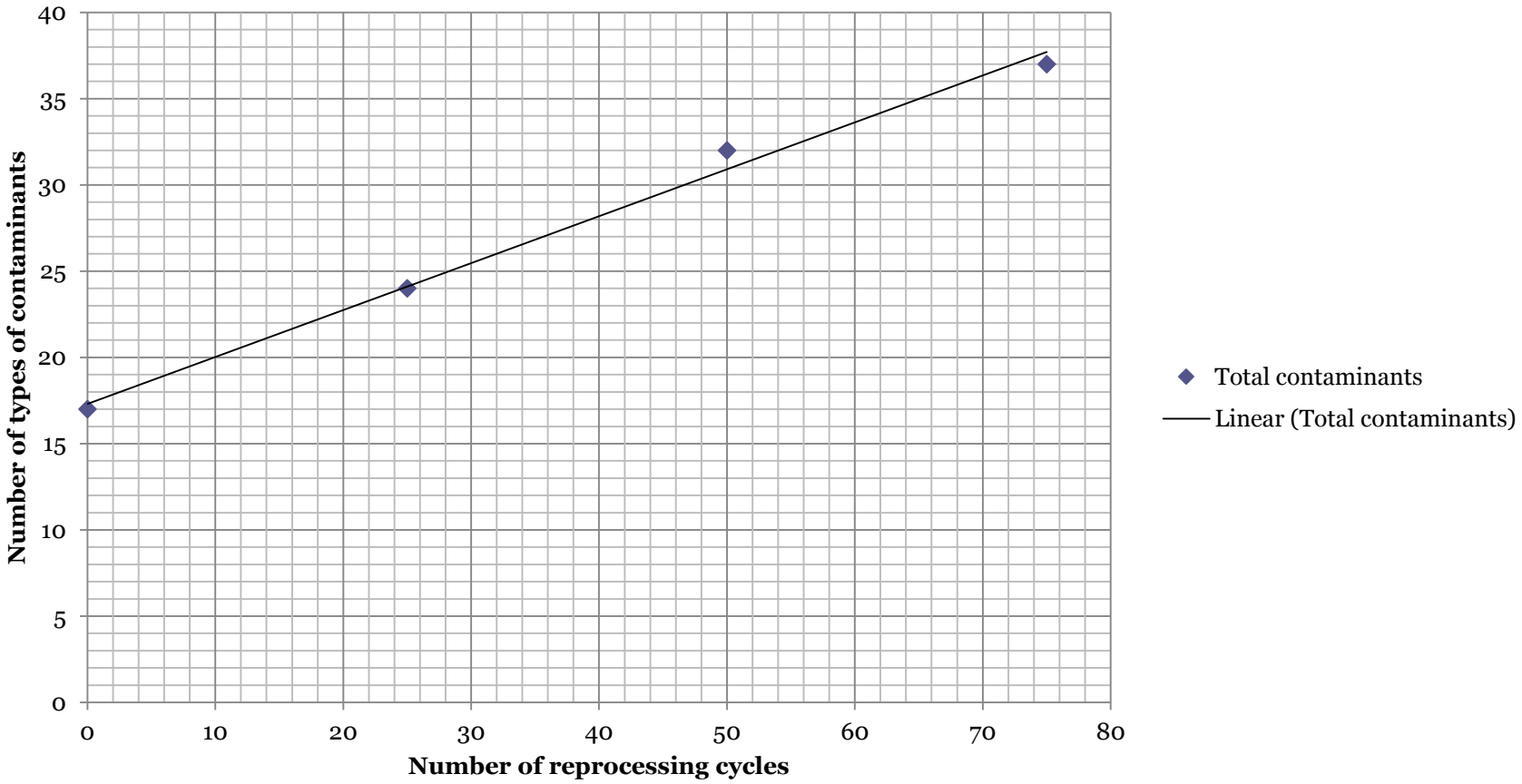
$$H = \frac{12}{n(n+1)} \sum_{j=1}^{k} \frac{R_j^2}{n_j} - 3(n+1)$$

Groups	Sum of the ranks in each group	n = total sample size k = the number of comparison groups R_j= sum of ranks in each group n_j = sample size of each group	Critical value Chi-square distribution table Reject H_o if: H ≥ 7.82 p<0.05 H ≥ 11.35 p<0.01 H ≥12.84 p<0.005	Outcome The medians are equal = Accept H_o The medians are not equal= Reject H_o
Rates of contamination				
Control	R_1=111.5	H=13.54	13.54>12.84	Reject H_o p< 0.005
High usage	R_2 = 172.5			
Moderate usage	R_3 = 243.5			
Low usage	R_4 =292.5			
Rates of corrosion, deterioration or damage				
Control	R_1=175	H=8.47	8.47>7.82	Reject H_o p< 0.05
High usage	R_2 = 110			
Moderate usage	R_3 = 239			
Low usage	R_4 =296			

Contaminates

Sample group & Number of contaminates (constant for each calculation)	**Number of reprocessing cycles**	**Correlation coefficient r, covariance r^2, slope and p value**	**Number of reprocessing cycles**	**Correlation coefficient r, covariance r^2, slope and p value**	**Number of reprocessing cycles**	**Correlation coefficient r, covariance r^2, slope and p value**	**Number of reprocessing cycles**	**Correlation coefficient r, covariance r^2, slope and p value**
Control 17	0	r = 0.94849	0	r = 0.92965	0	r = 0.99613	0	r = 0.99613
High usage 24	5	r^2= 0.89963	1	r^2= 0.86425	25	r^2= 0.99227	100	r^2= 0.99227
Moderate usage 32	25	Slope = 0.36774	51	Slope = 0.16718	50	Slope = 0.272	200	Slope = 0.068
Low usage 37	50	p<0.00001	103	p<0.00001	75	p<0.00001	300	p<0.00001

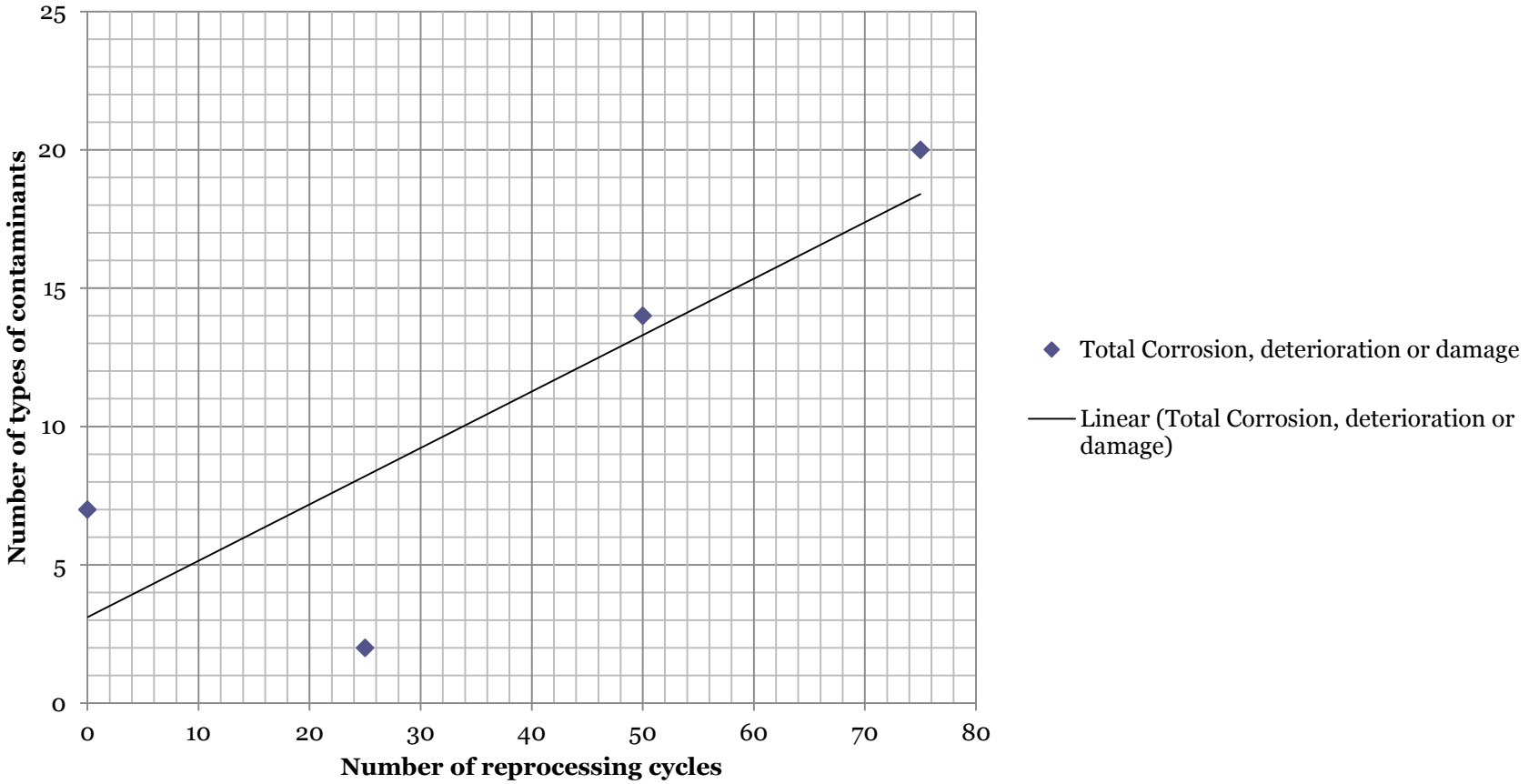
Contaminates



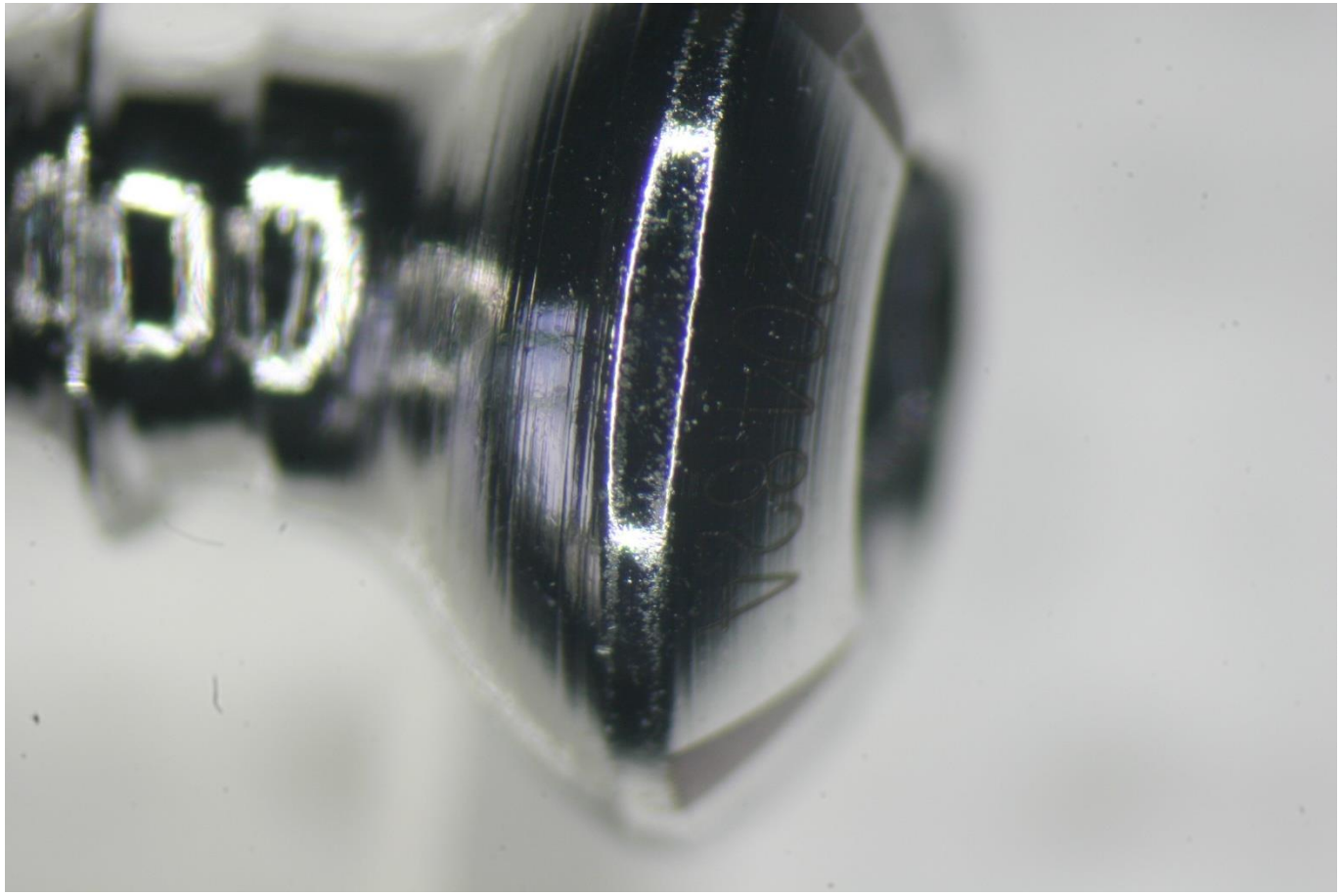
Corrosion, deterioration, damage

Sample group & Number of contaminates (constant for each calculation)	**Number of reprocessing cycles**	**Correlation coefficient r, covariance r^2, slope and p value**	**Number of reprocessing cycles**	**Correlation coefficient r, covariance r^2, slope and p value**	**Number of reprocessing cycles**	**Correlation coefficient r, covariance r^2, slope and p value**	**Number of reprocessing cycles**	**Correlation coefficient r, covariance r^2, slope and p value**
Control 7	0	r = 0.92934	0	r = 0.95672	0	r = 0.8345	0	r = 0.8345
High usage 12	5	r^2= 0.86367	1	r^2= 0.91532	25	r^2= 0.69639	100	r^2= 0.69639
Moderate usage 14	25	Slope = 0.32258	51	Slope = 0.15403	50	Slope = 0.204	200	Slope = 0.051
Low usage 20	50	p<0.00001	103	p<0.00001	75	p<0.00001	300	p<0.00001

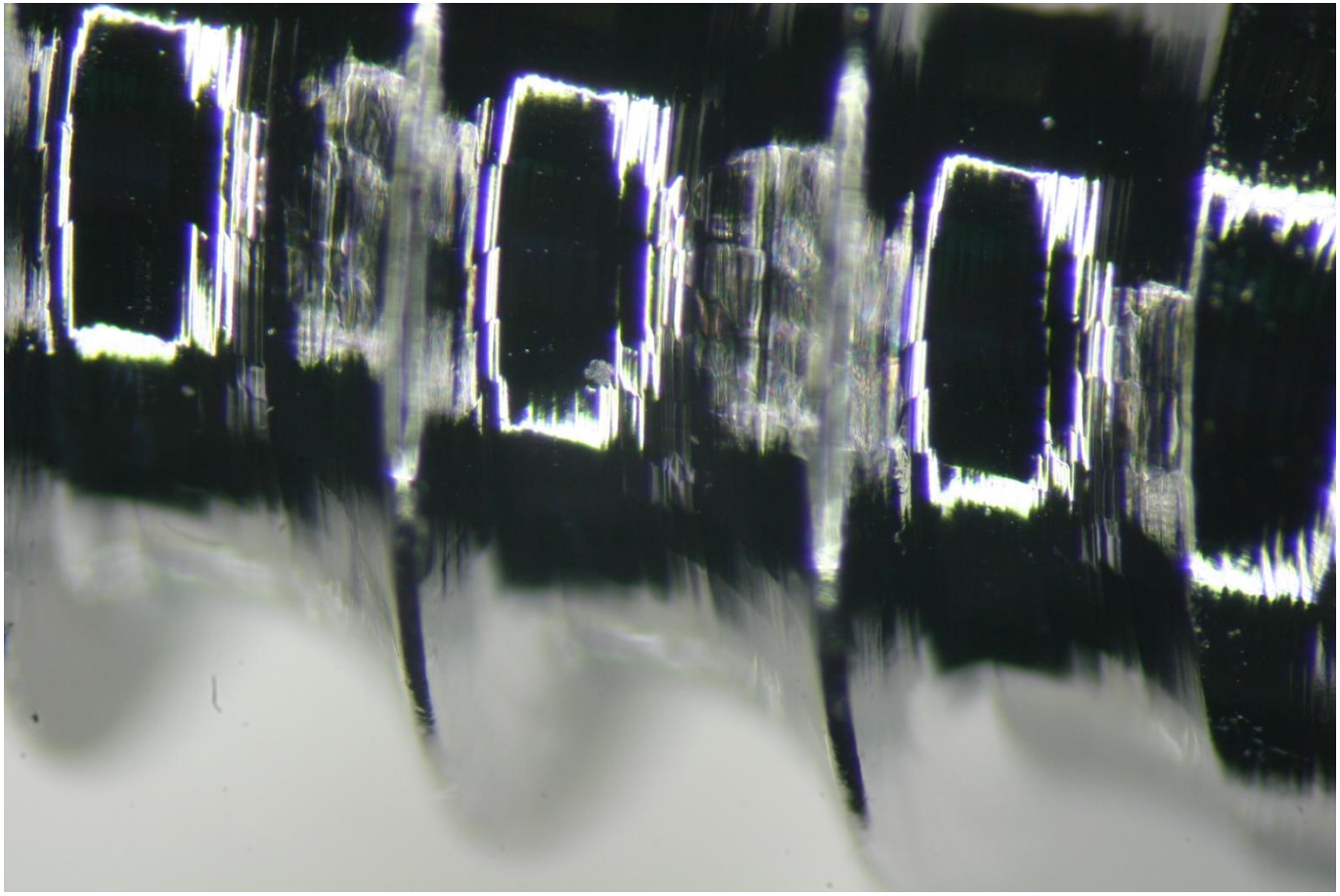
Corrosion, deterioration, damage



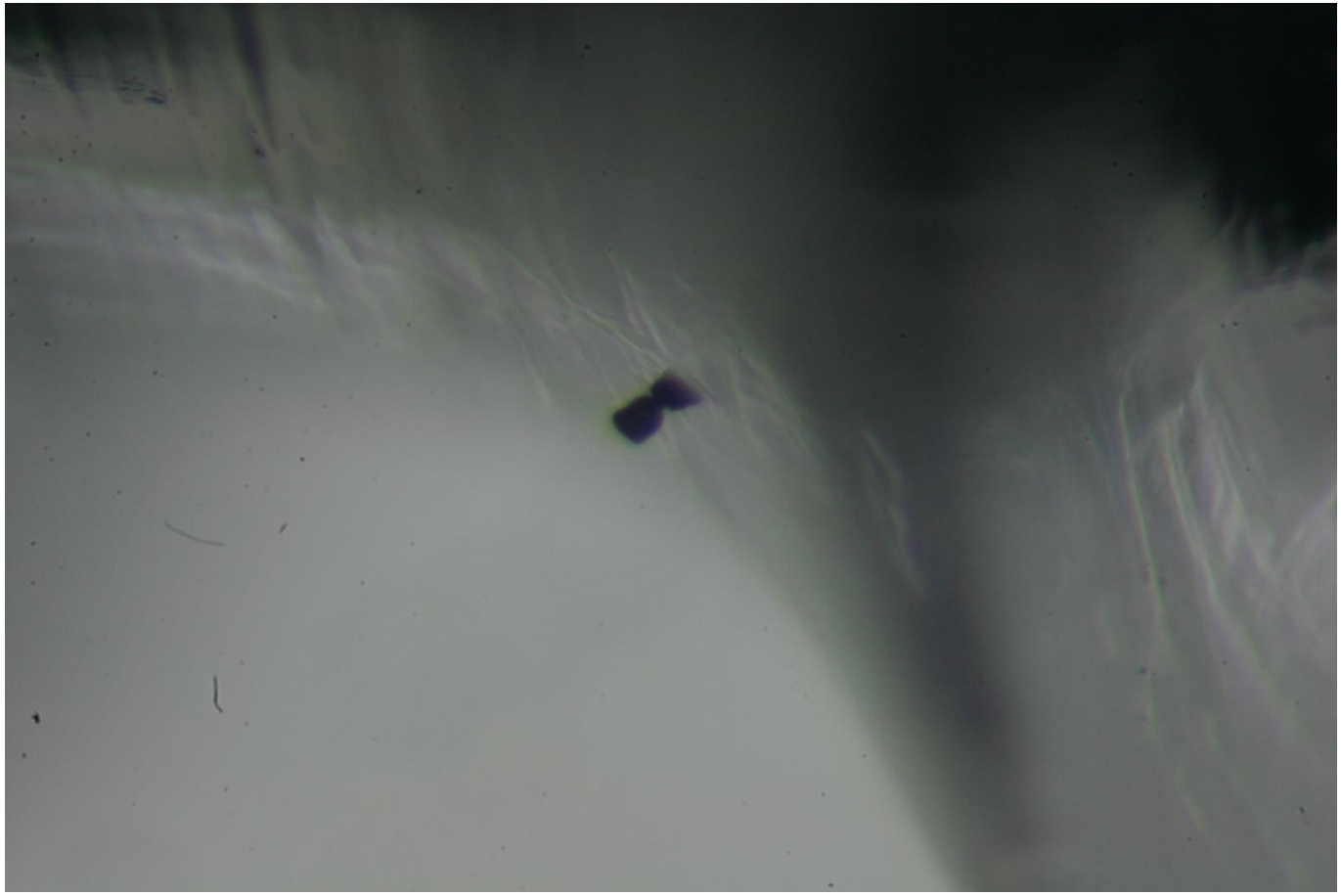
Control – marks on surface



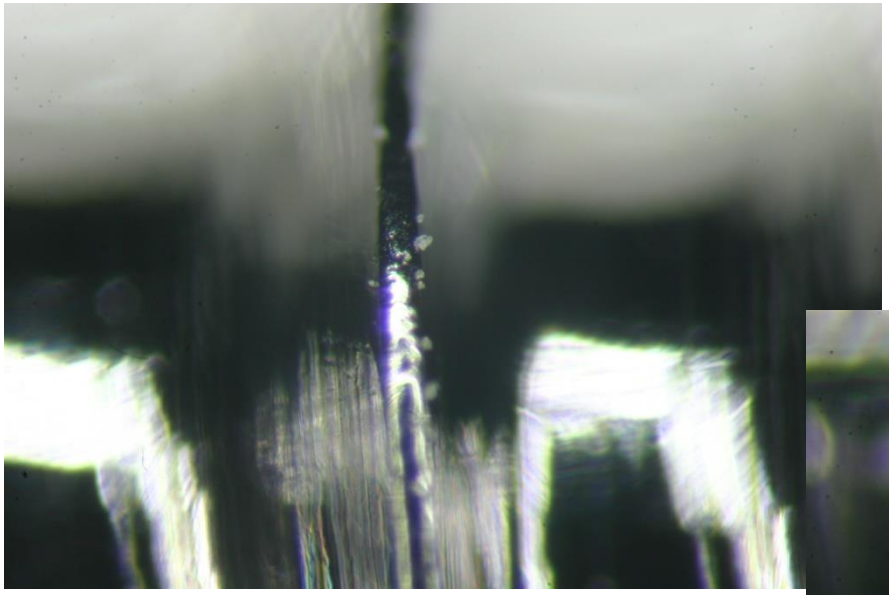
Control – greyish residue

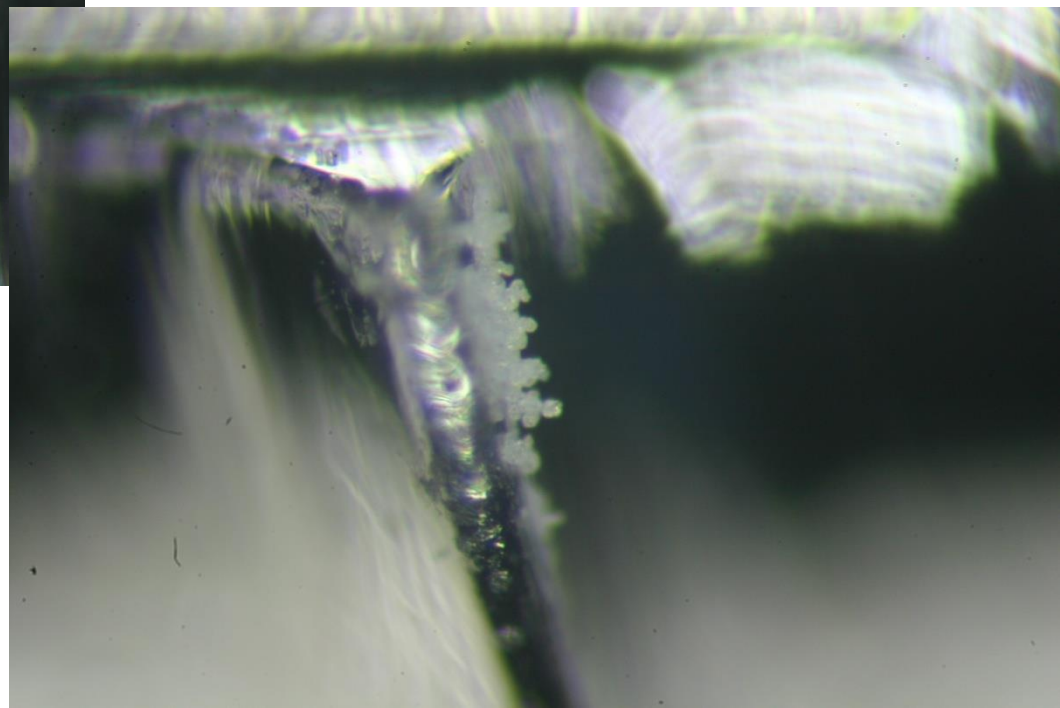


Control - black deposit

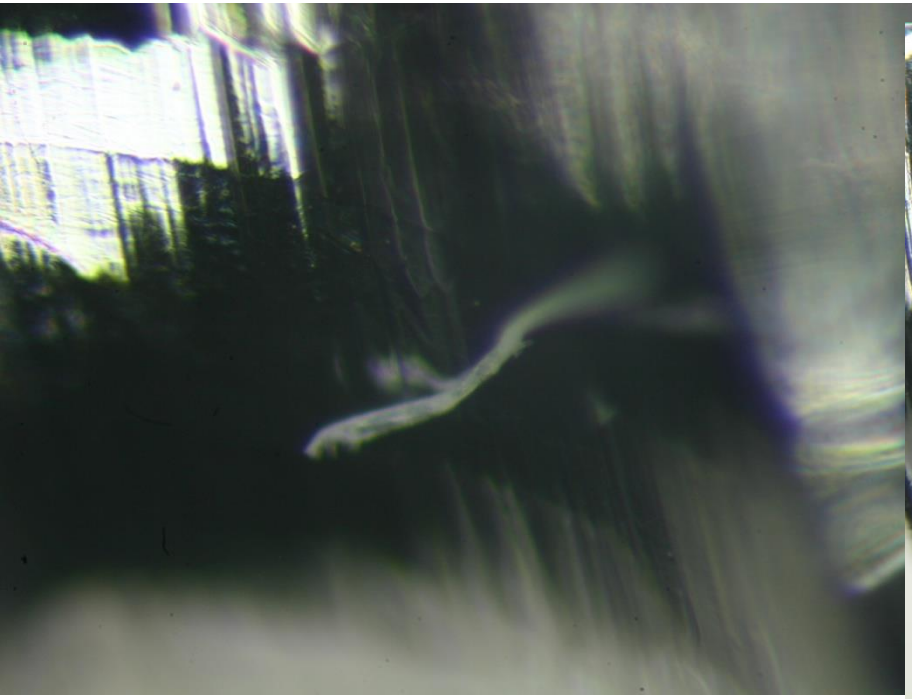


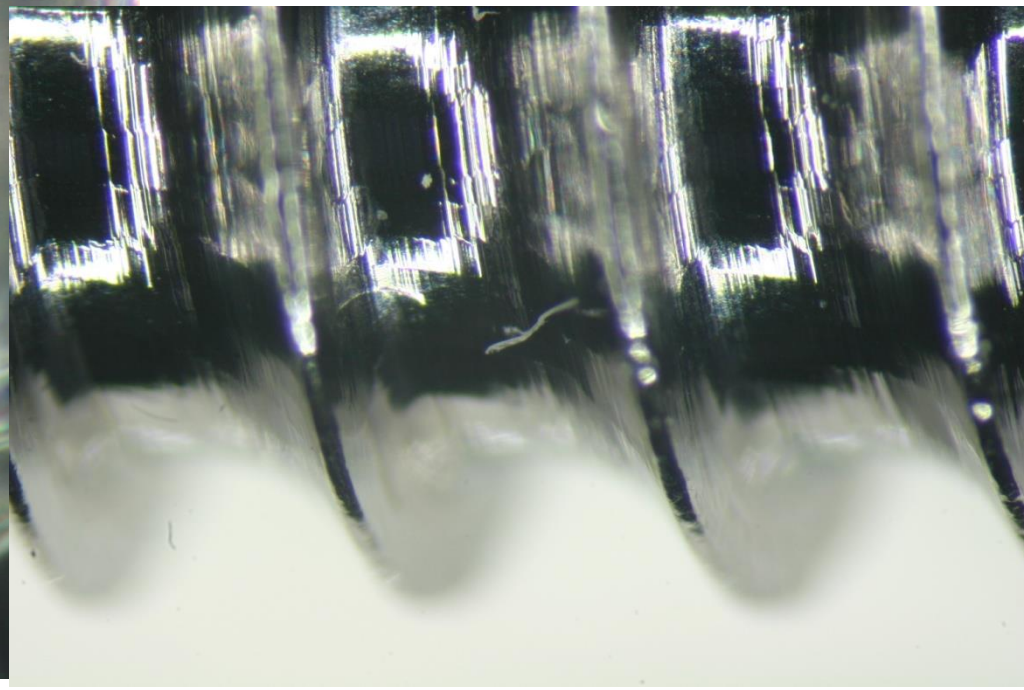
Control – crystalline deposits



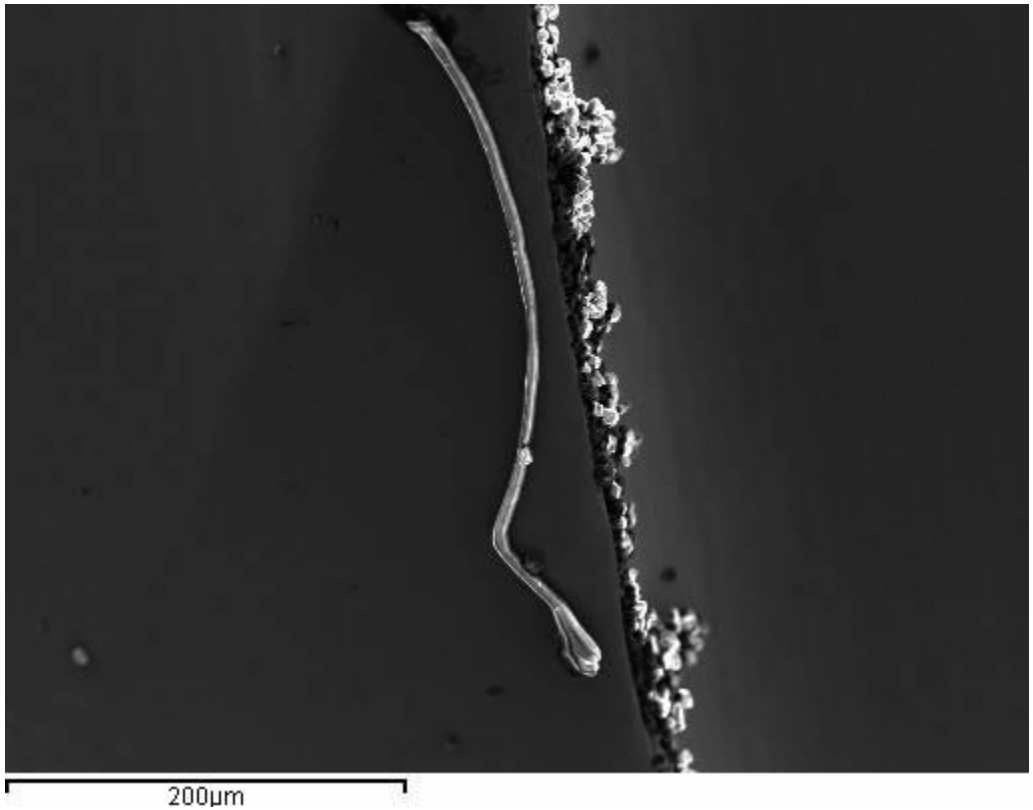


Control - fibre

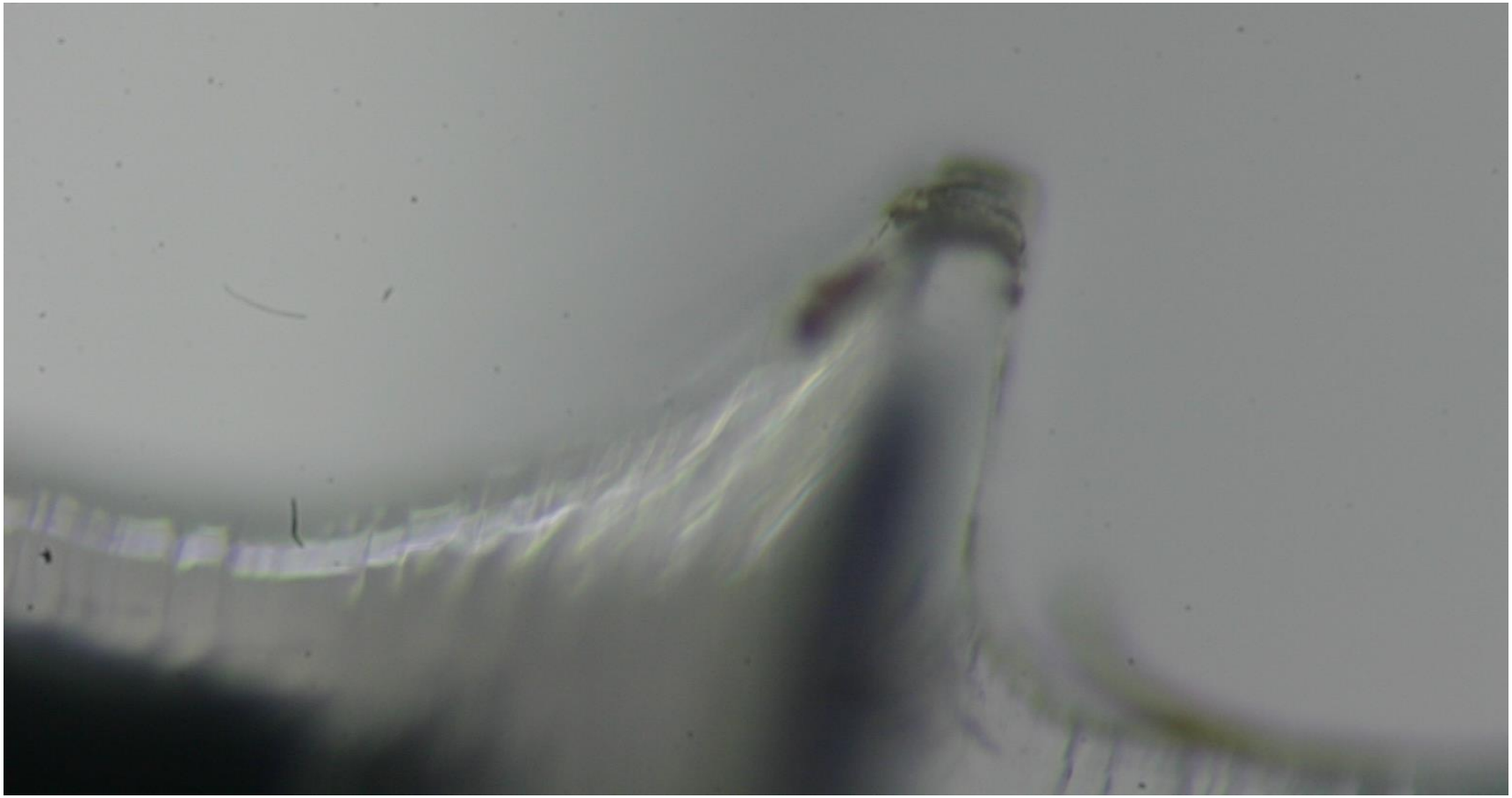


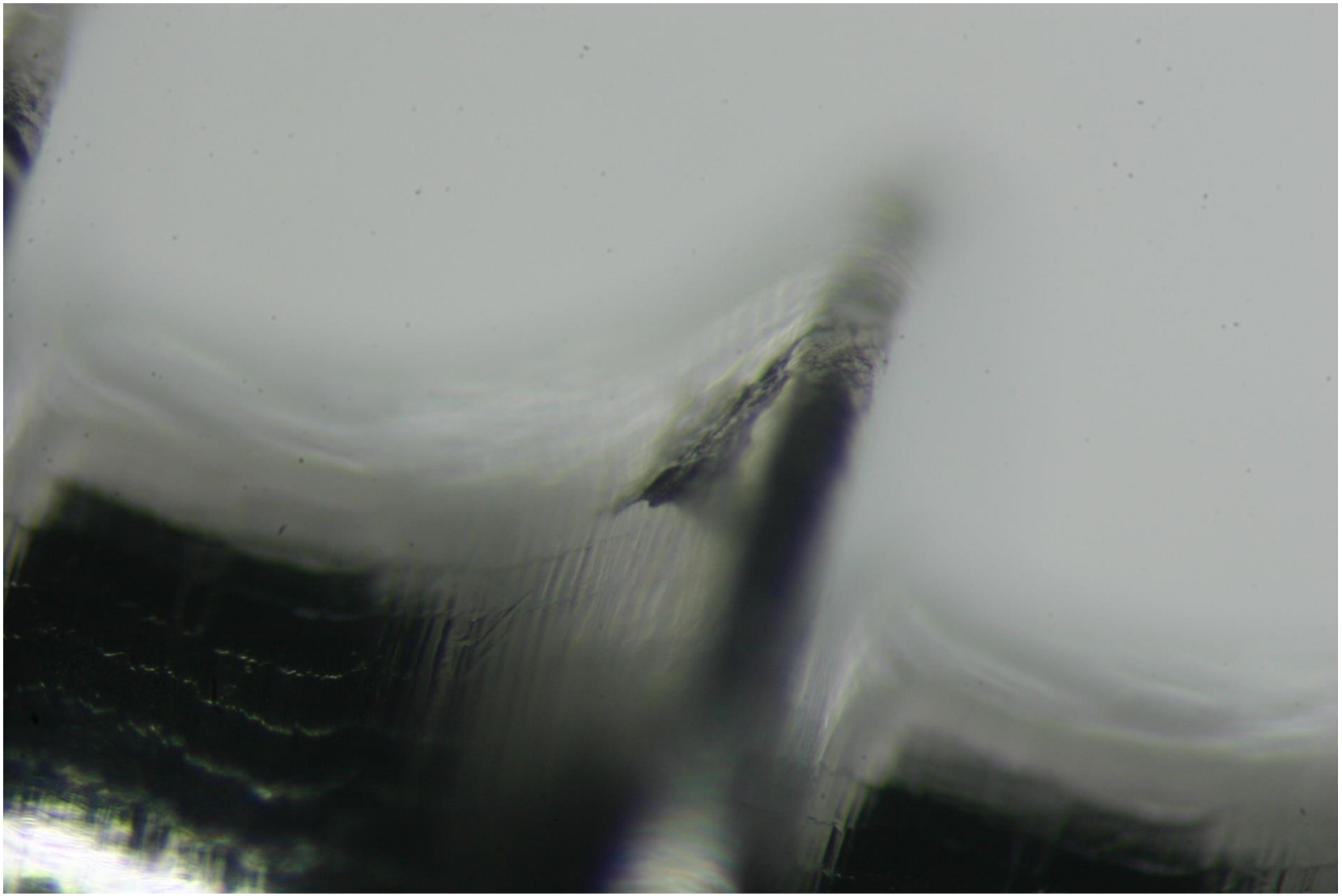


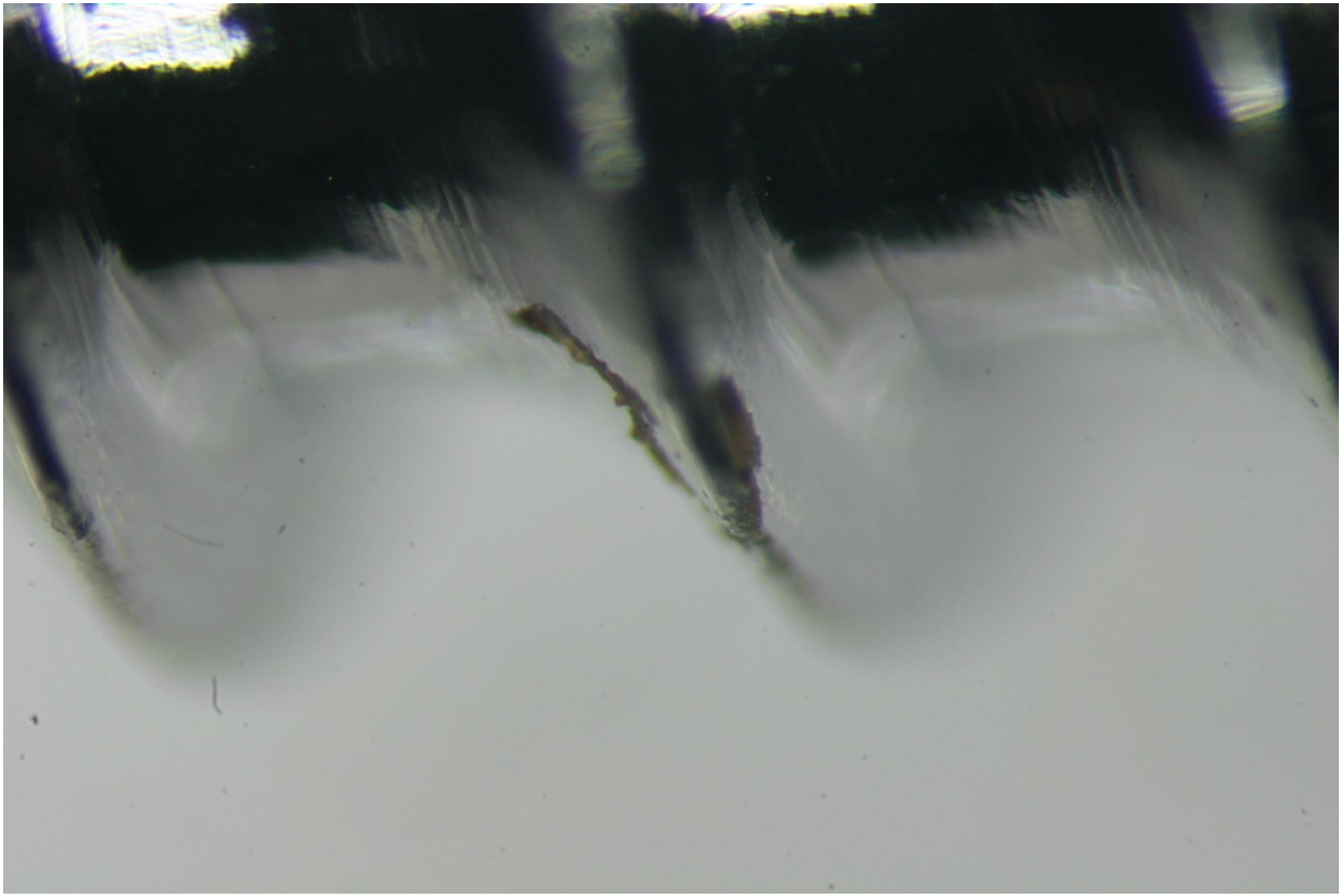
Control – crystalline deposits & fibre

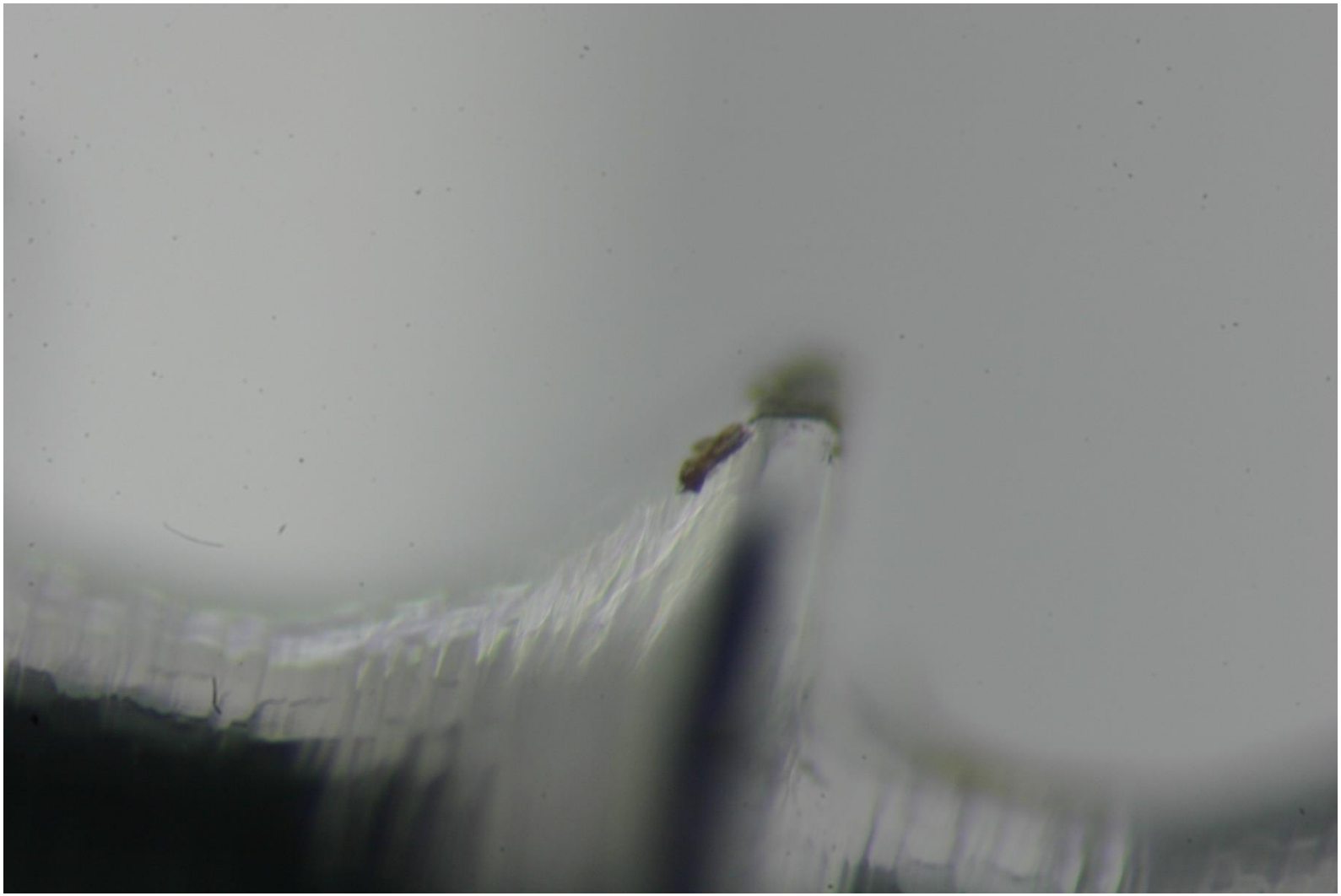


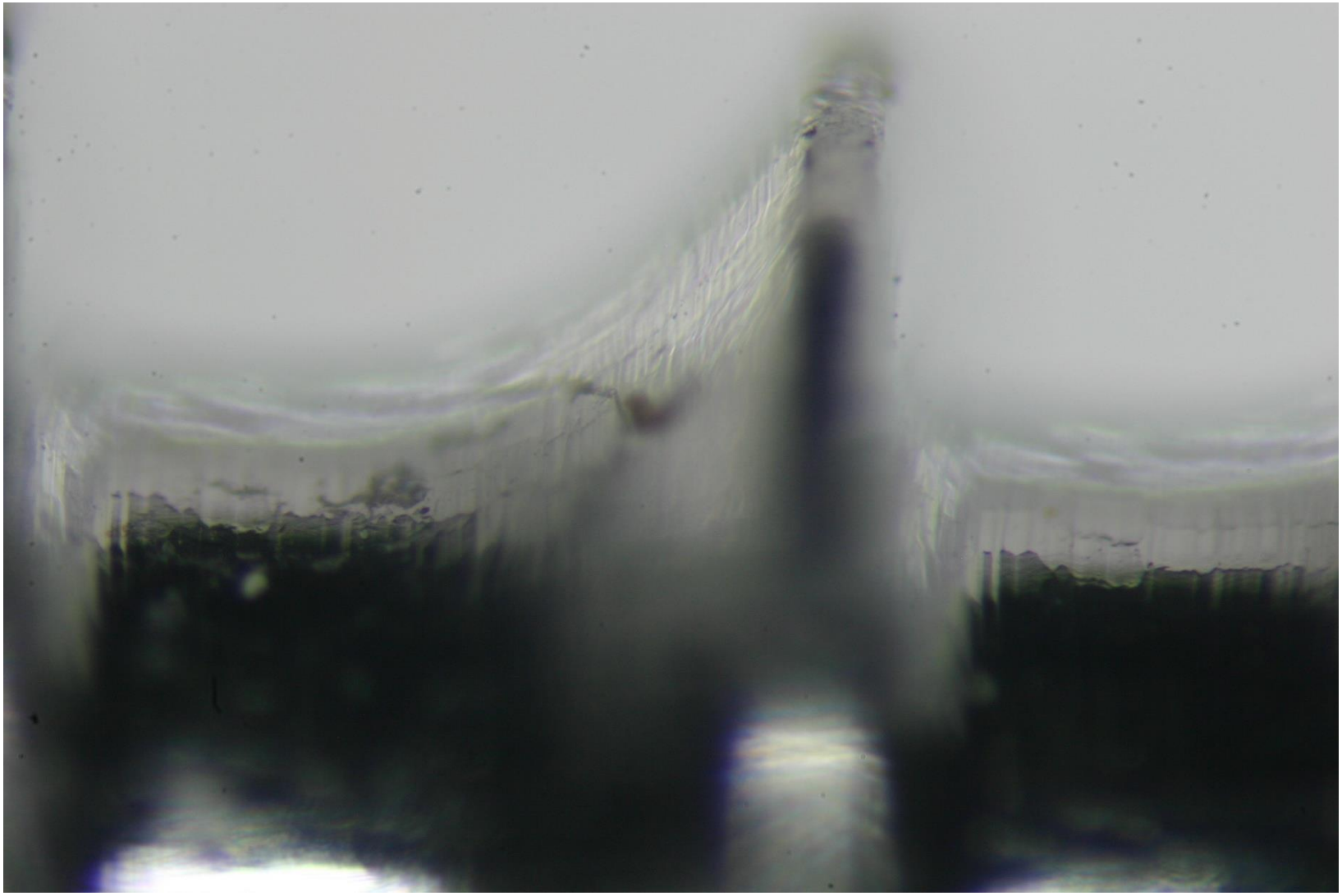
Reprocessed screws

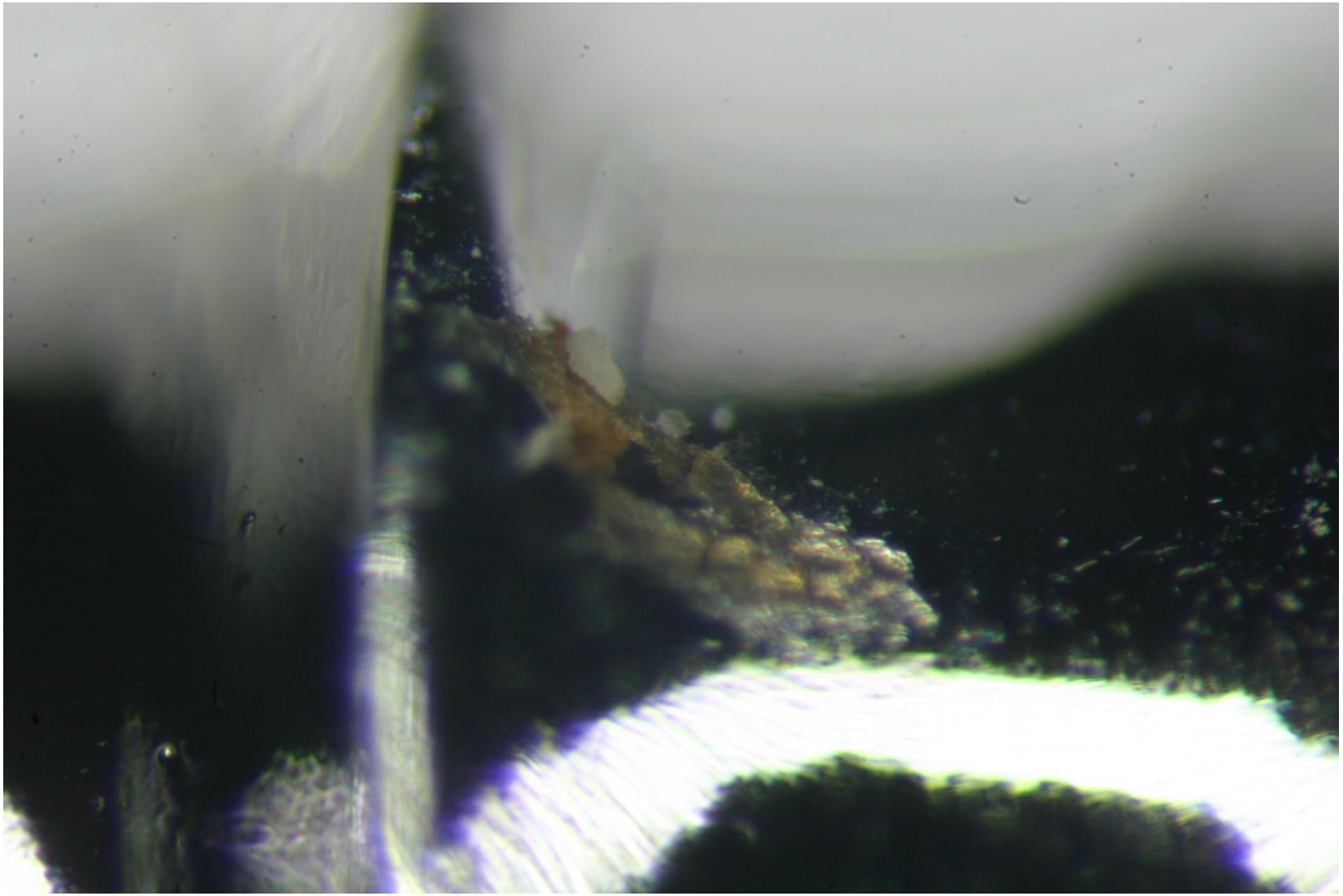


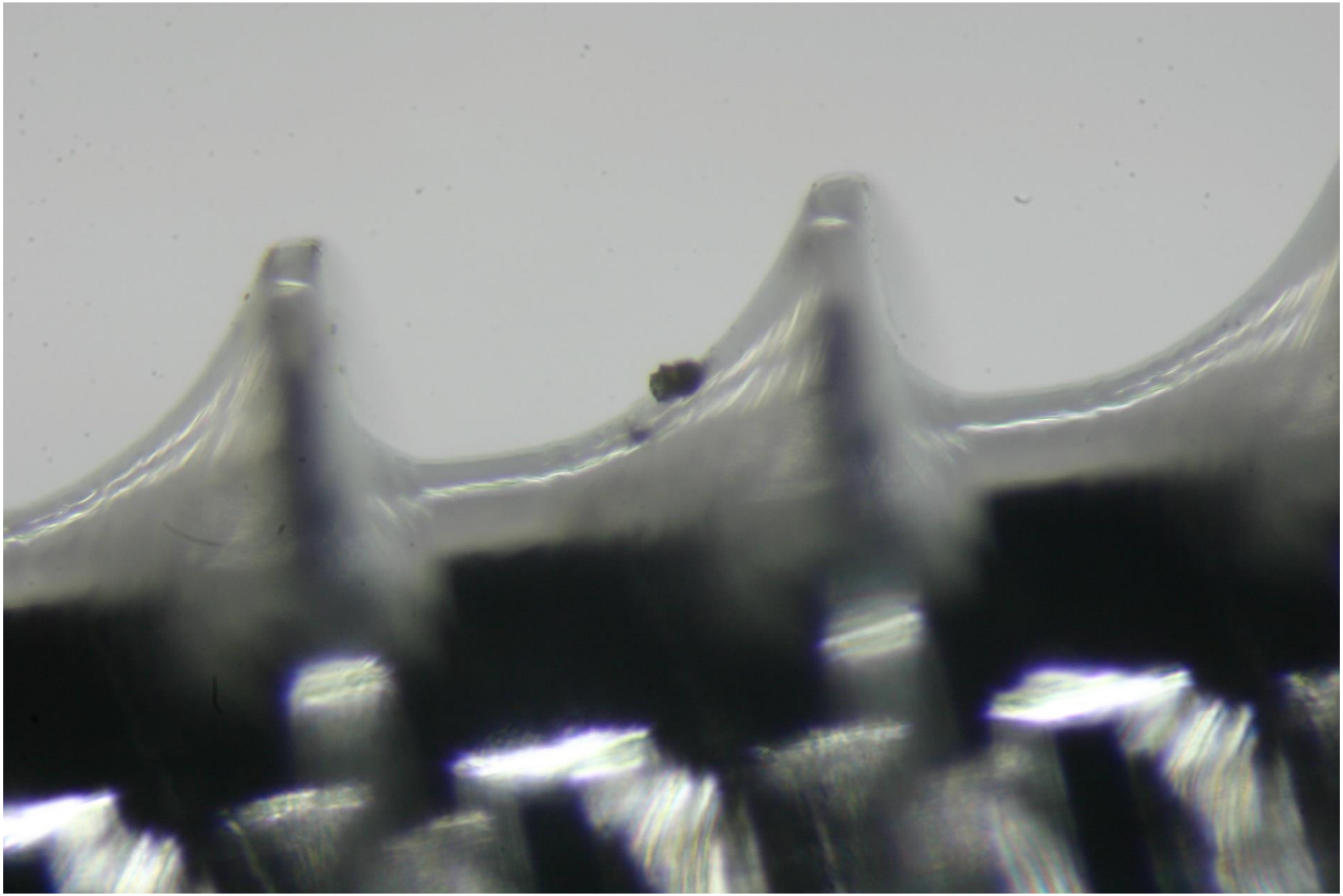


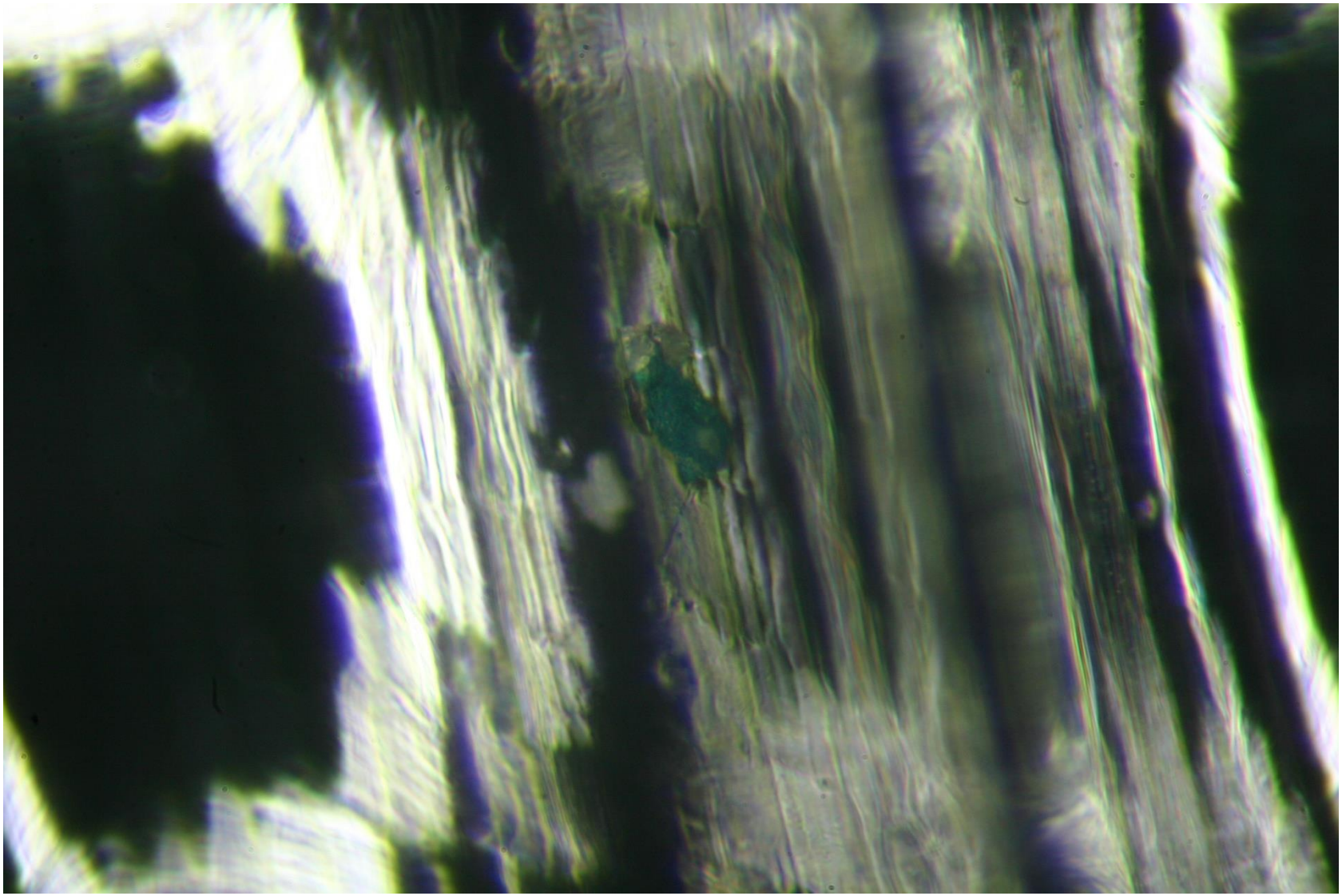


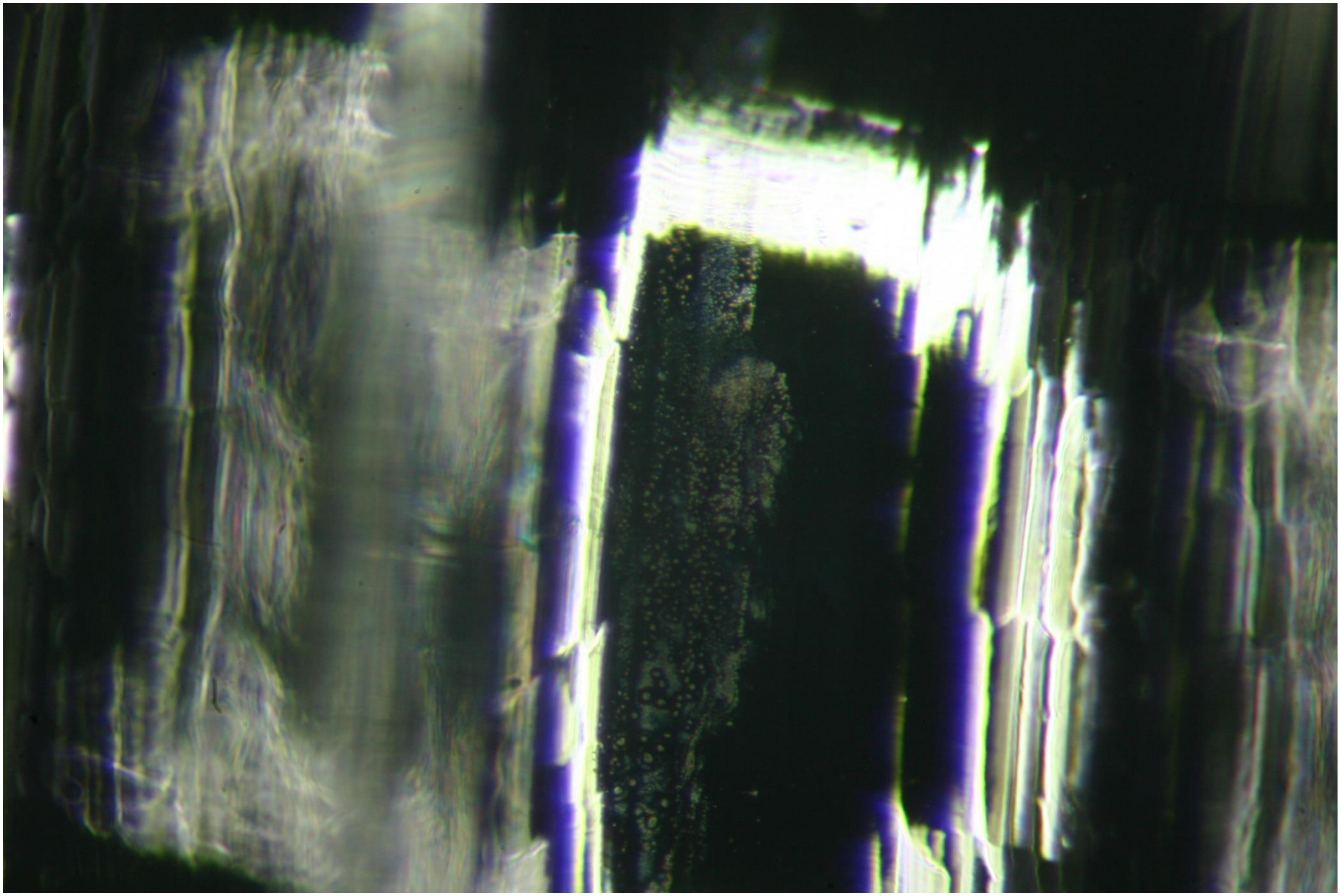


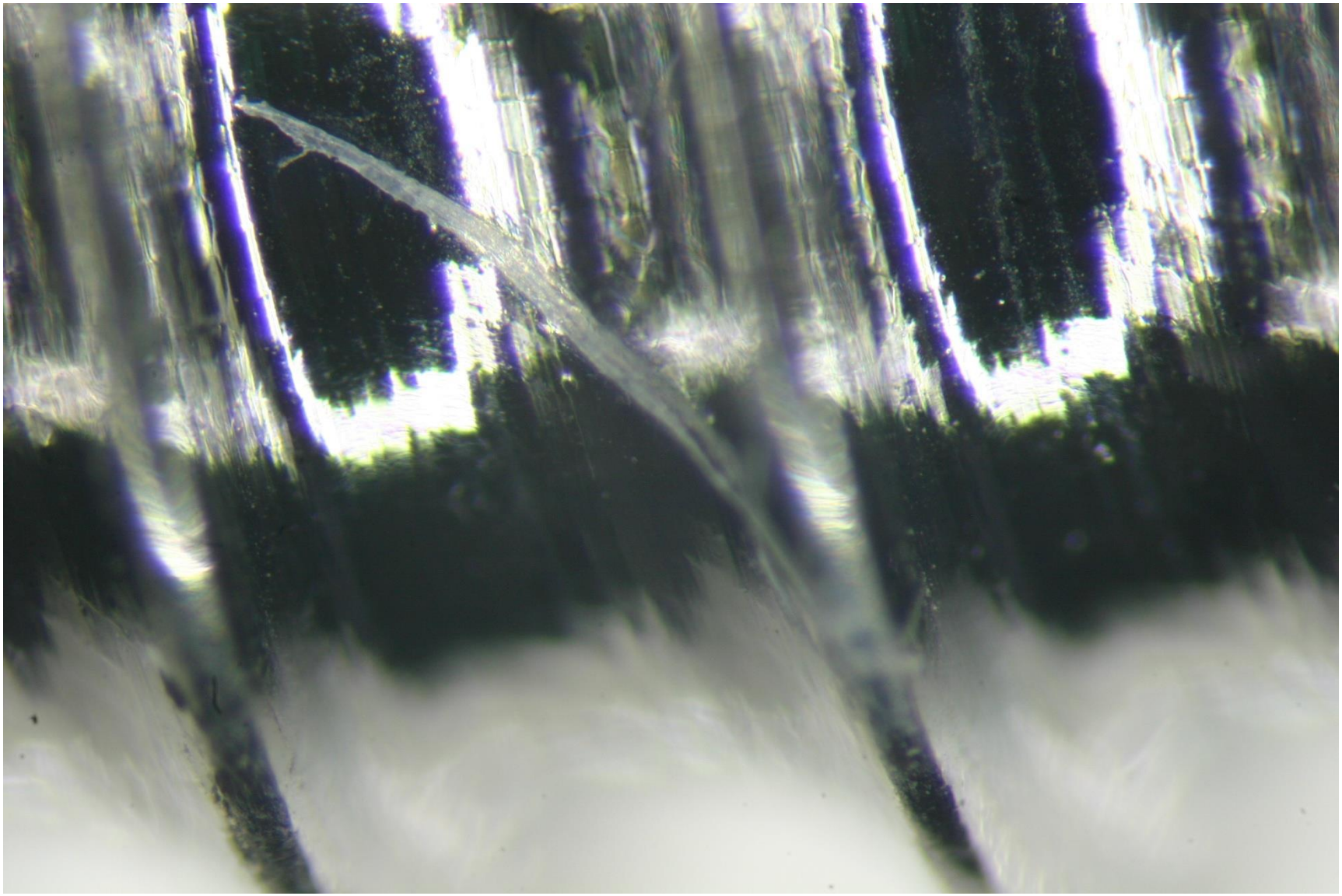


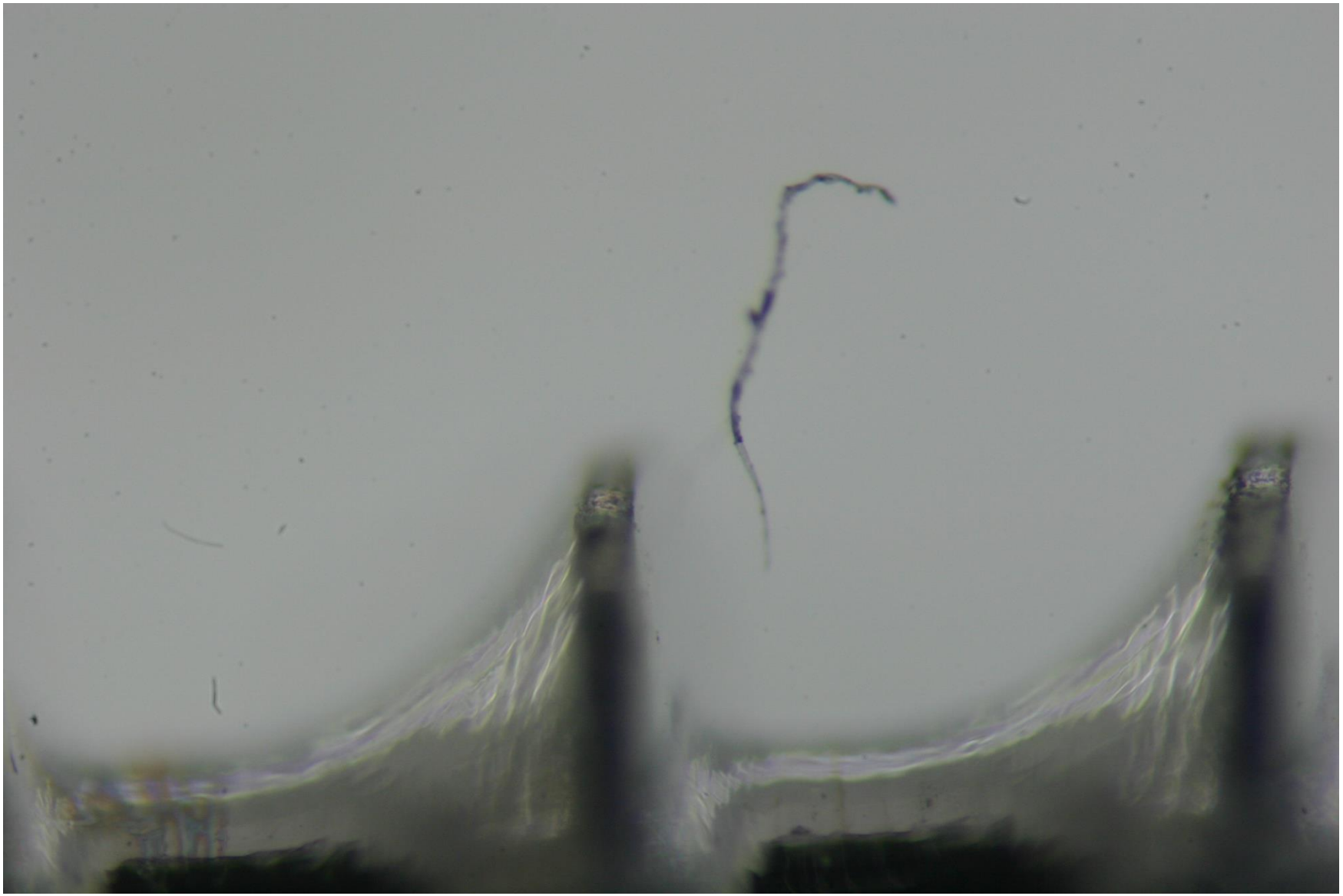


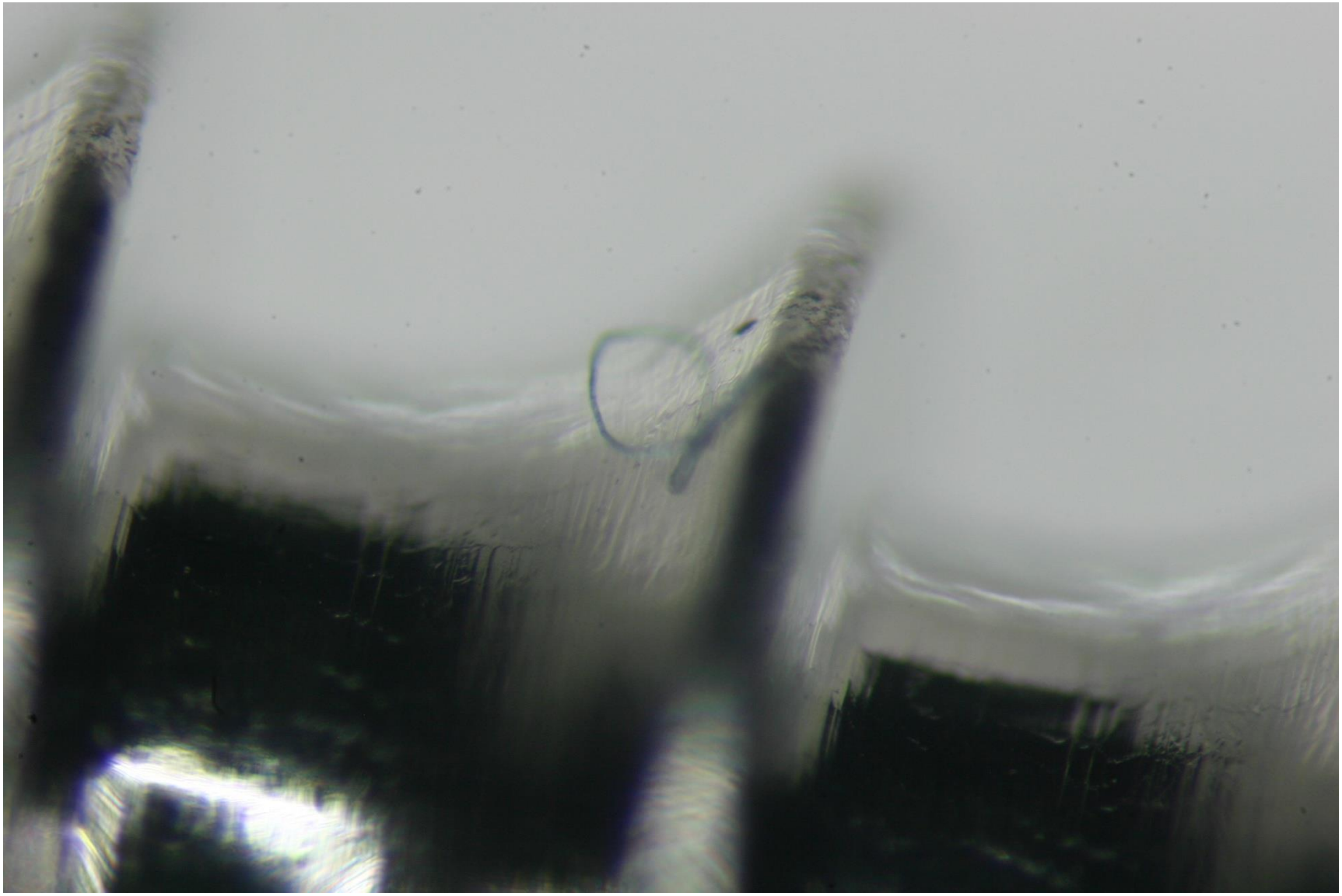


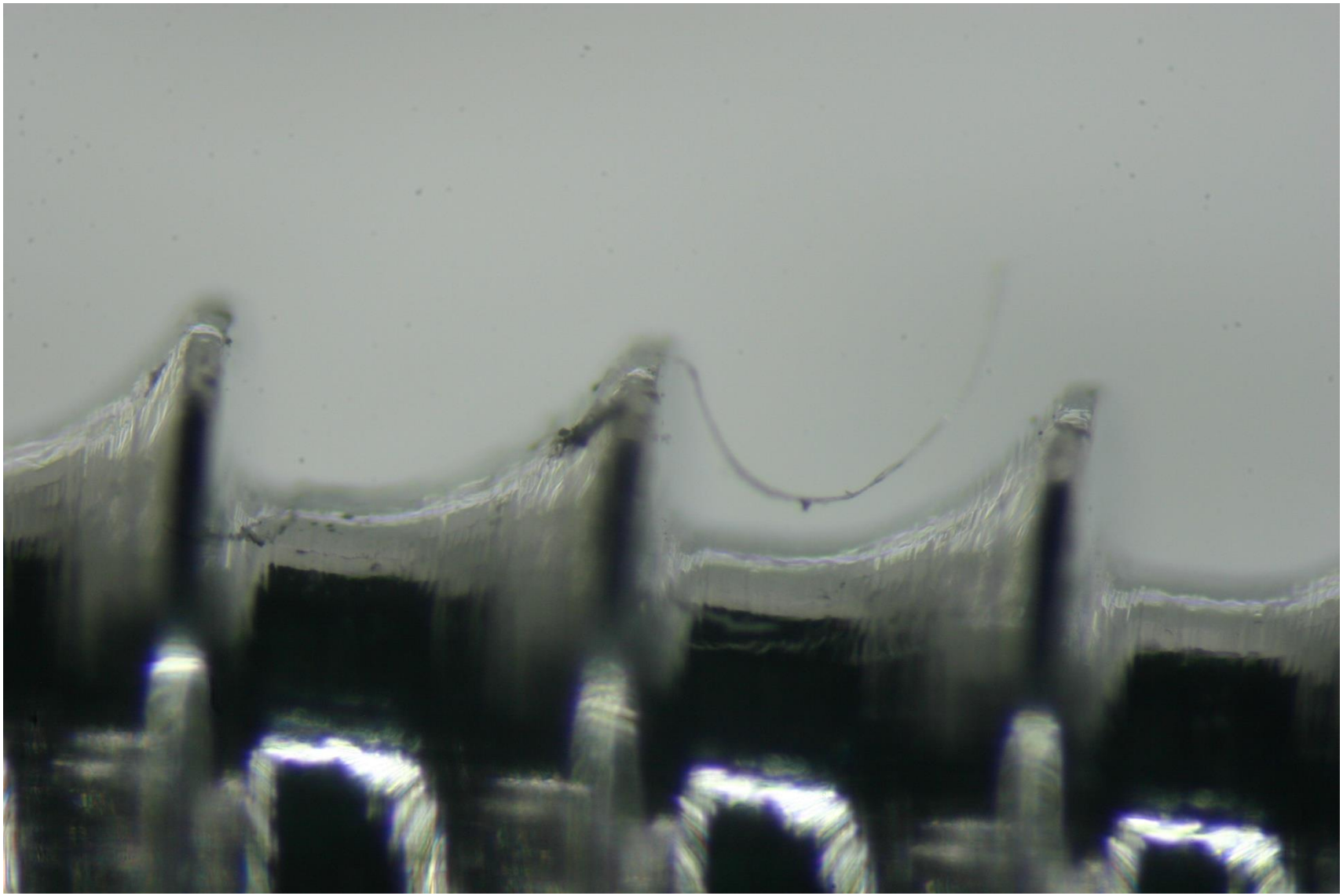


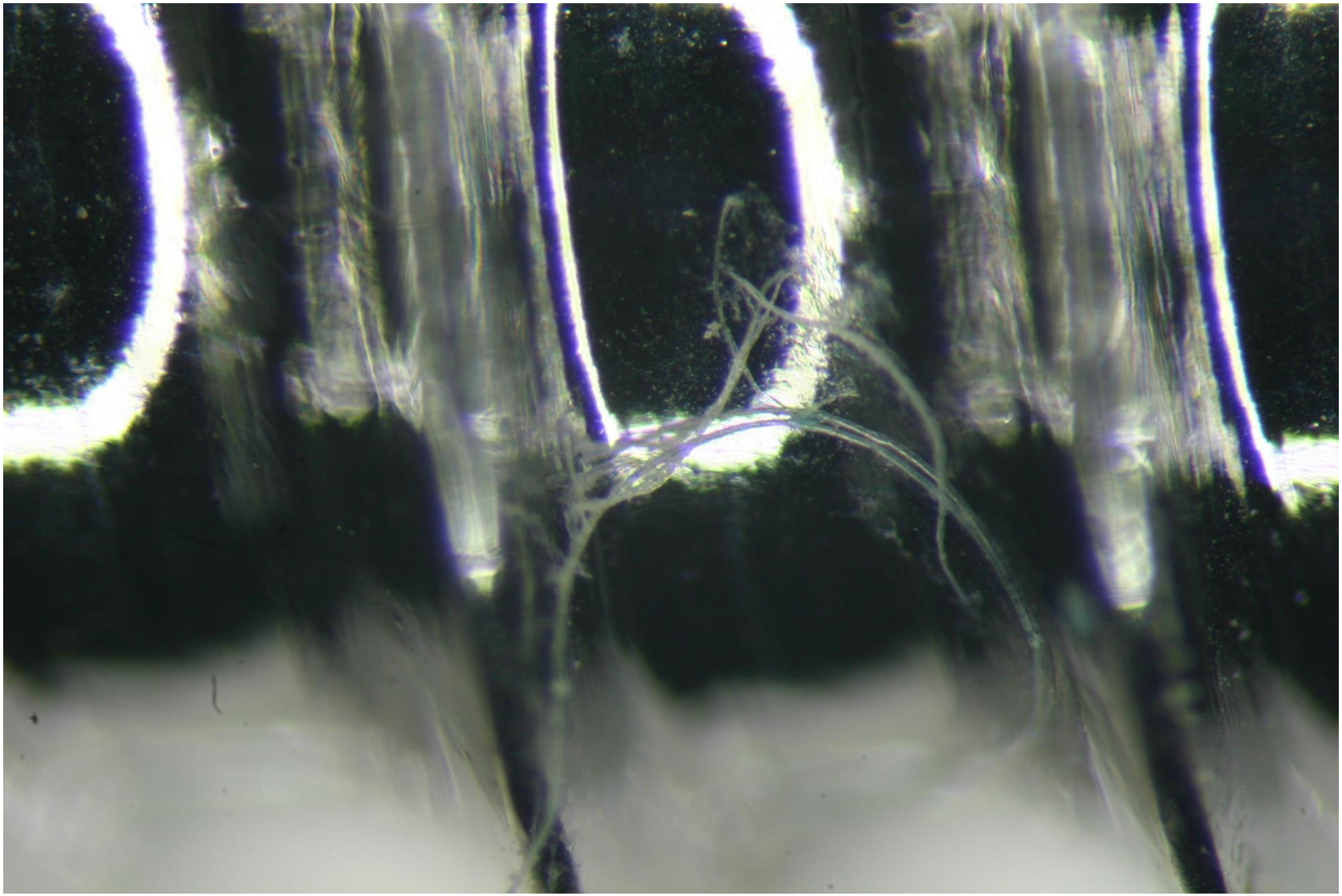


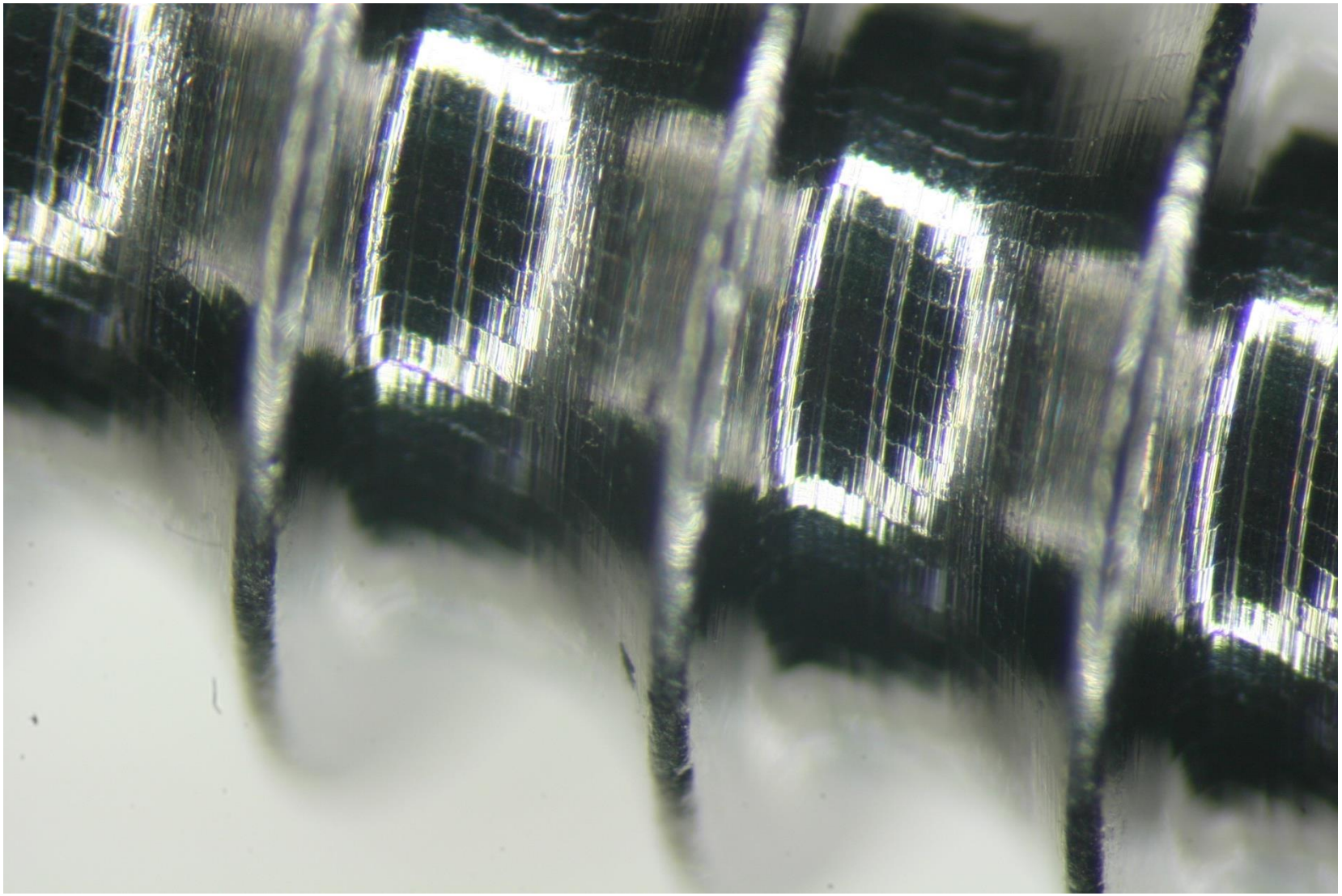


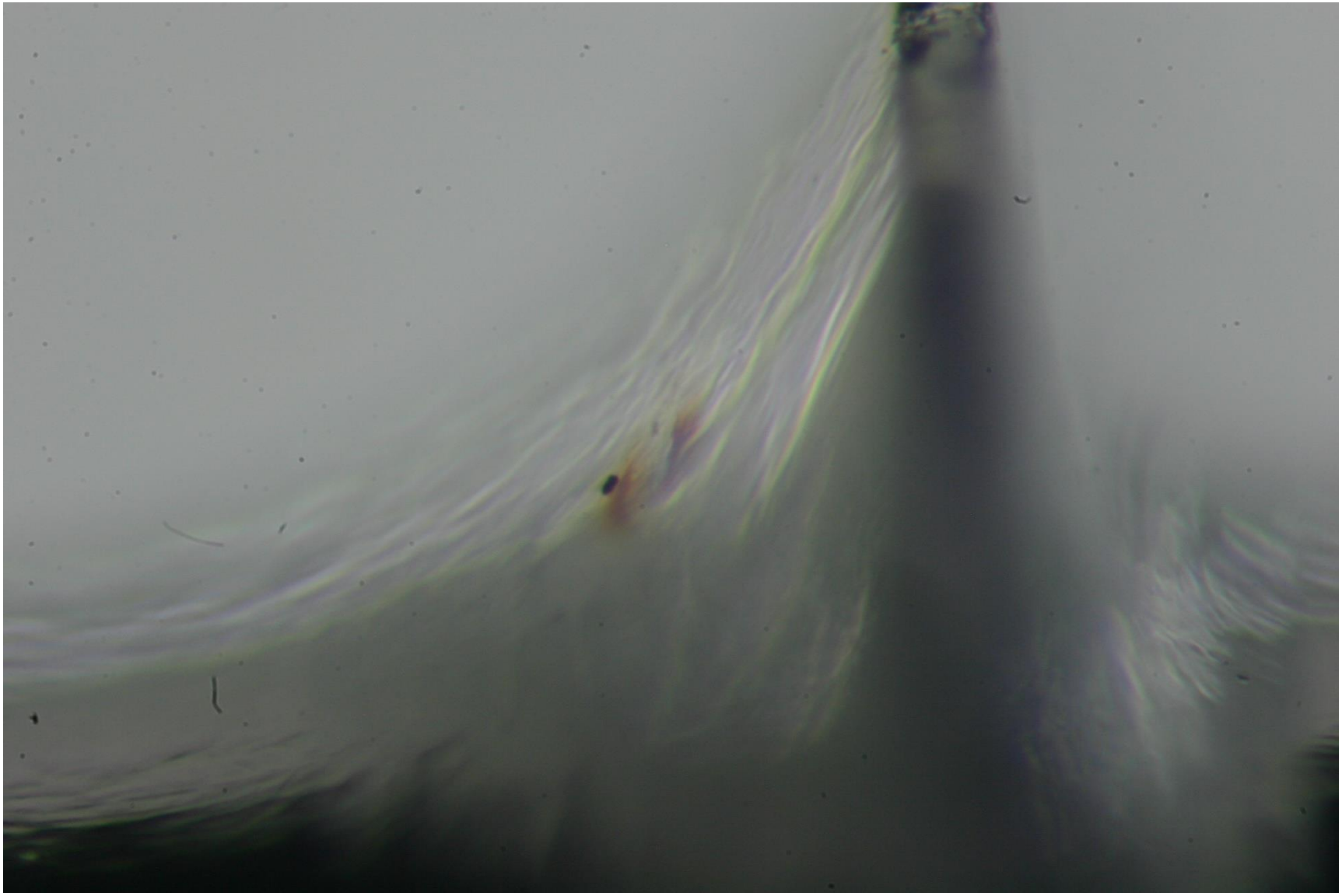


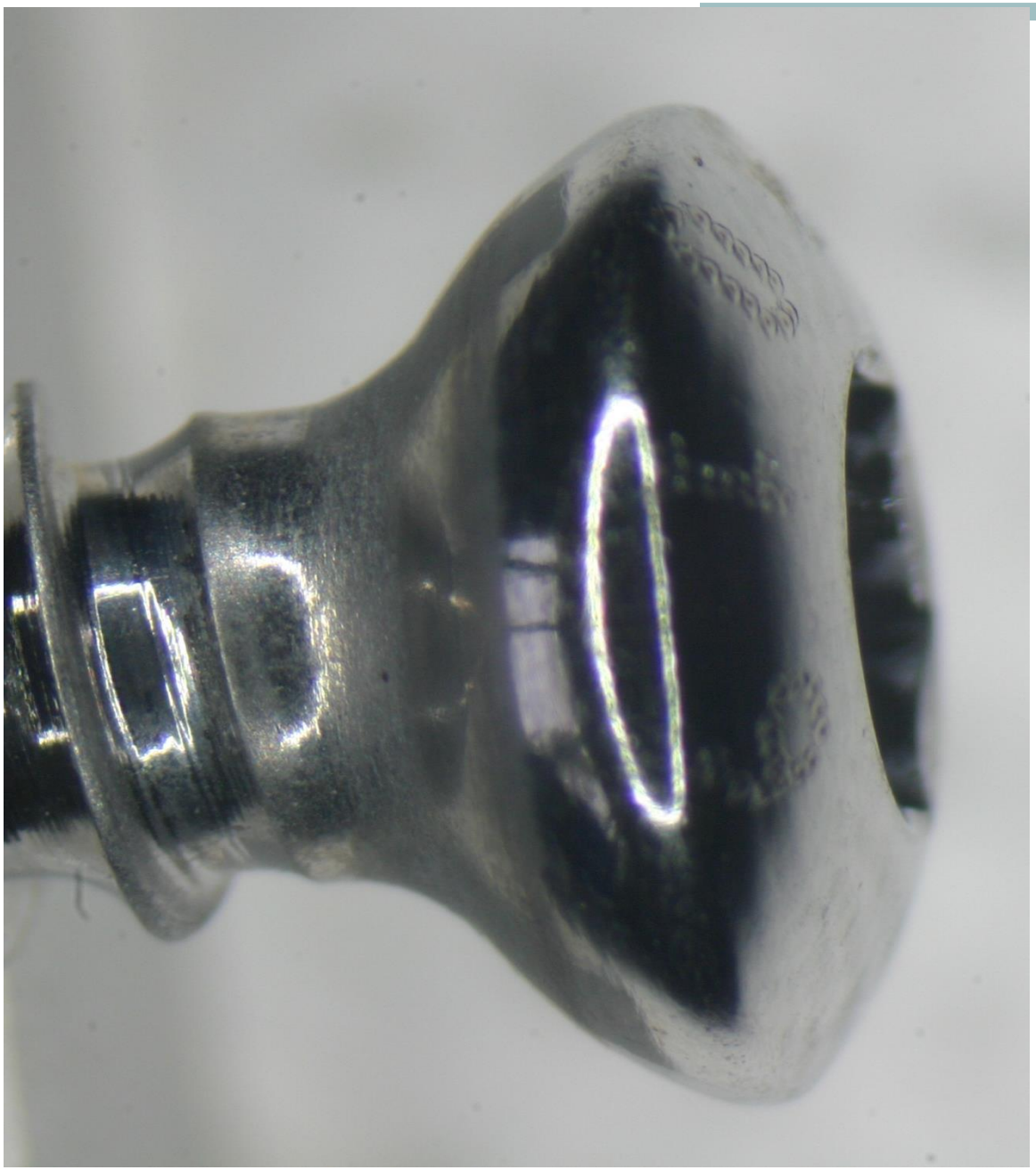






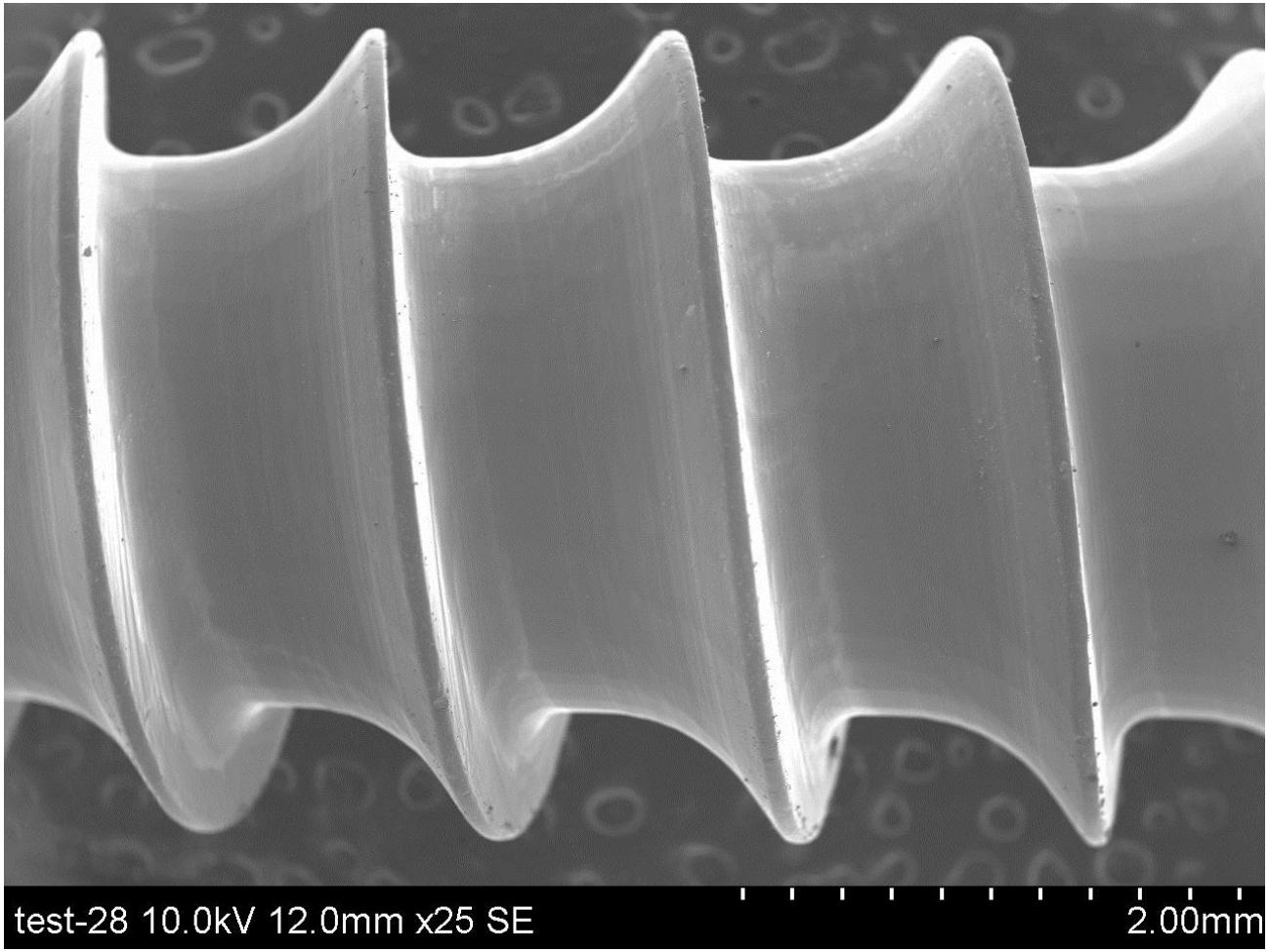




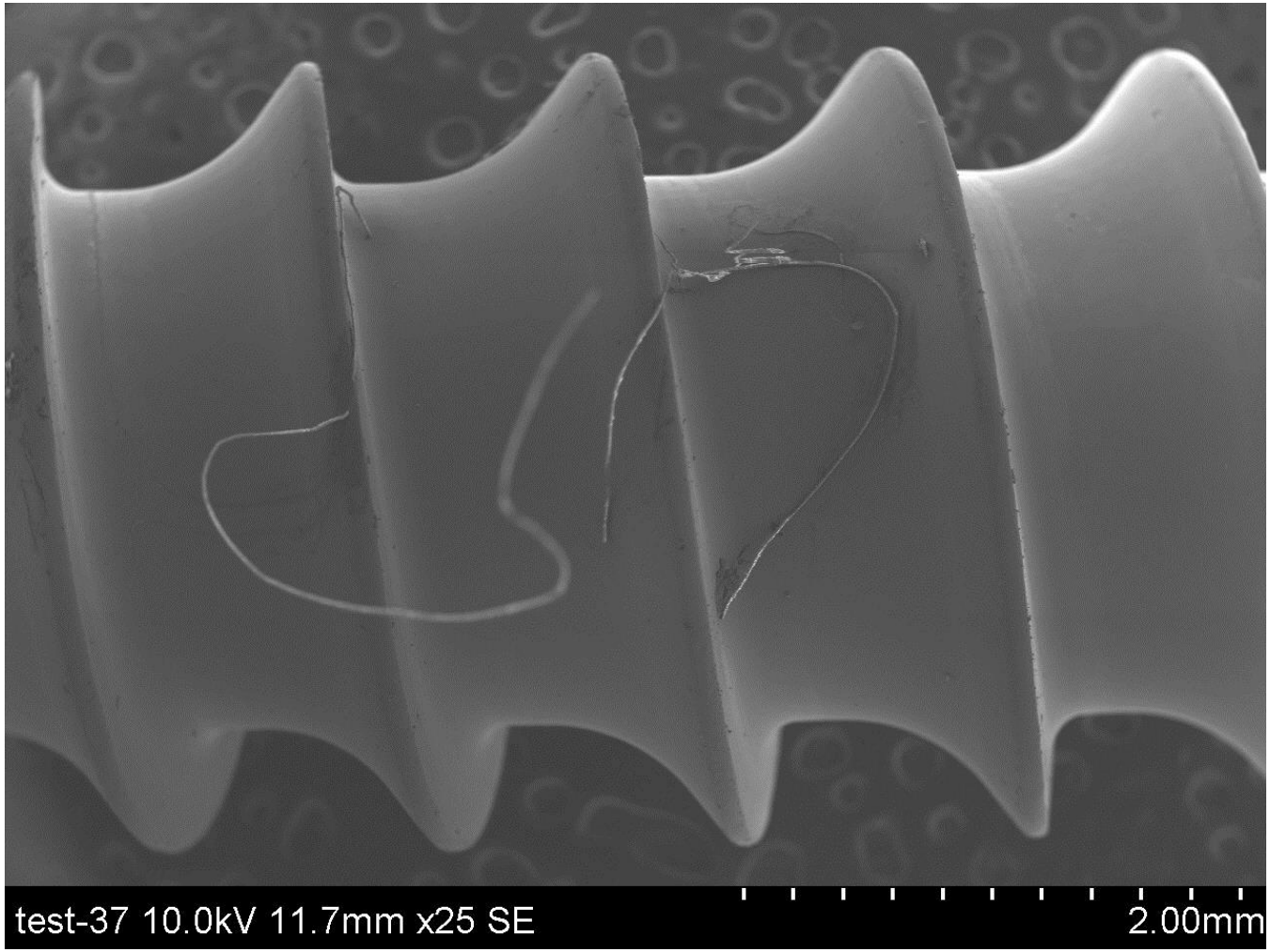


Electron microscope images

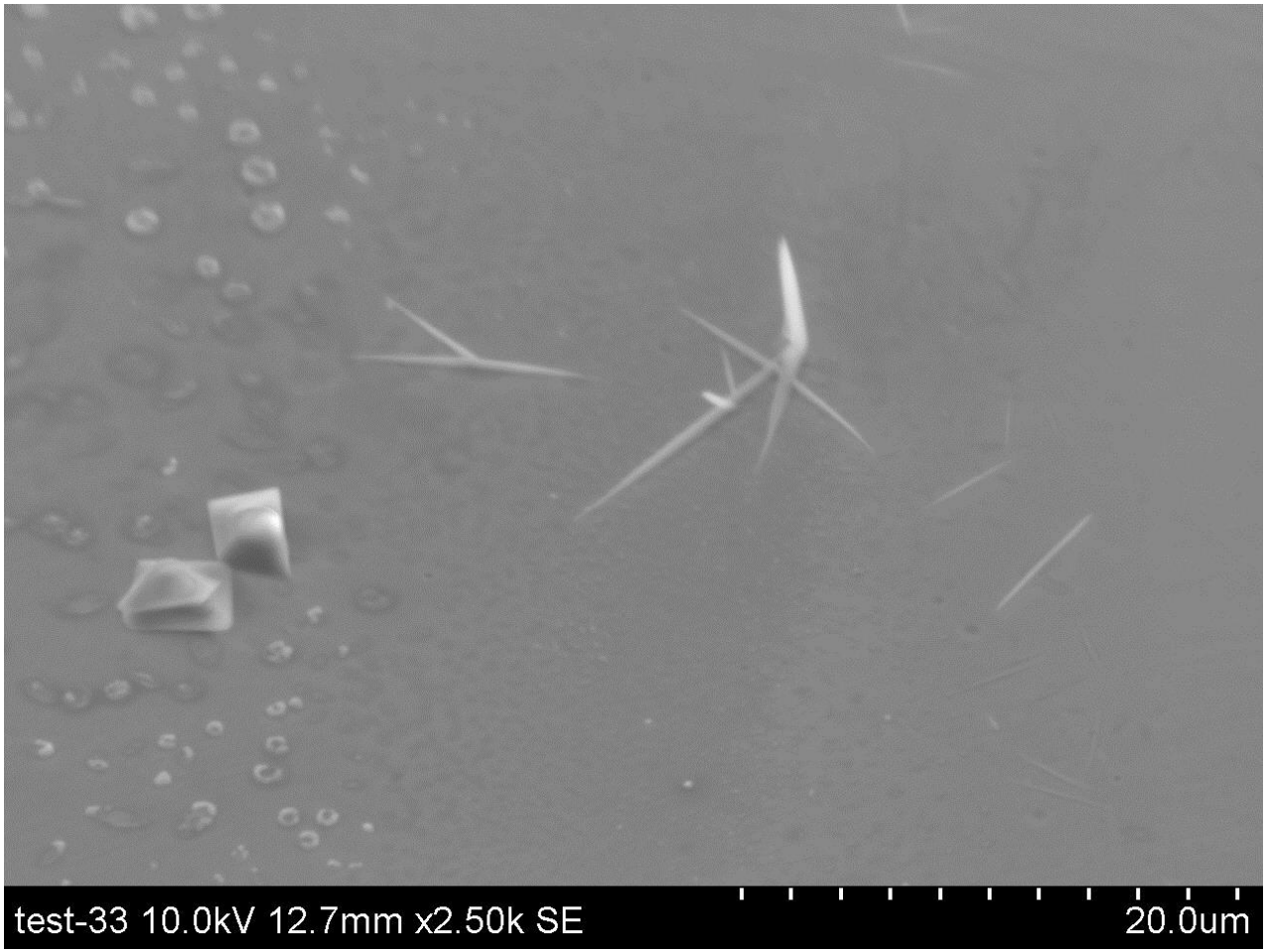
Control screw



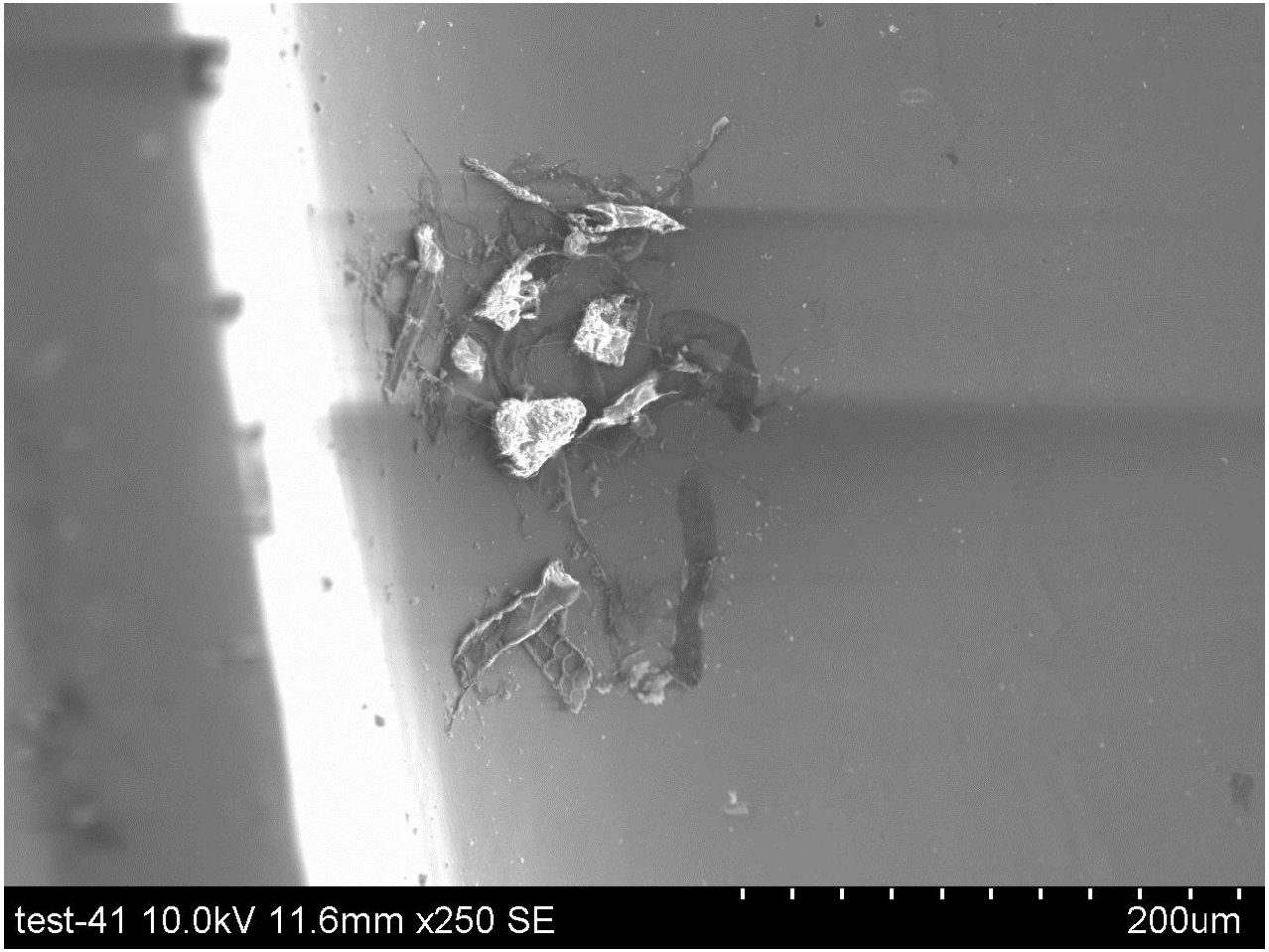
Reprocessed screw



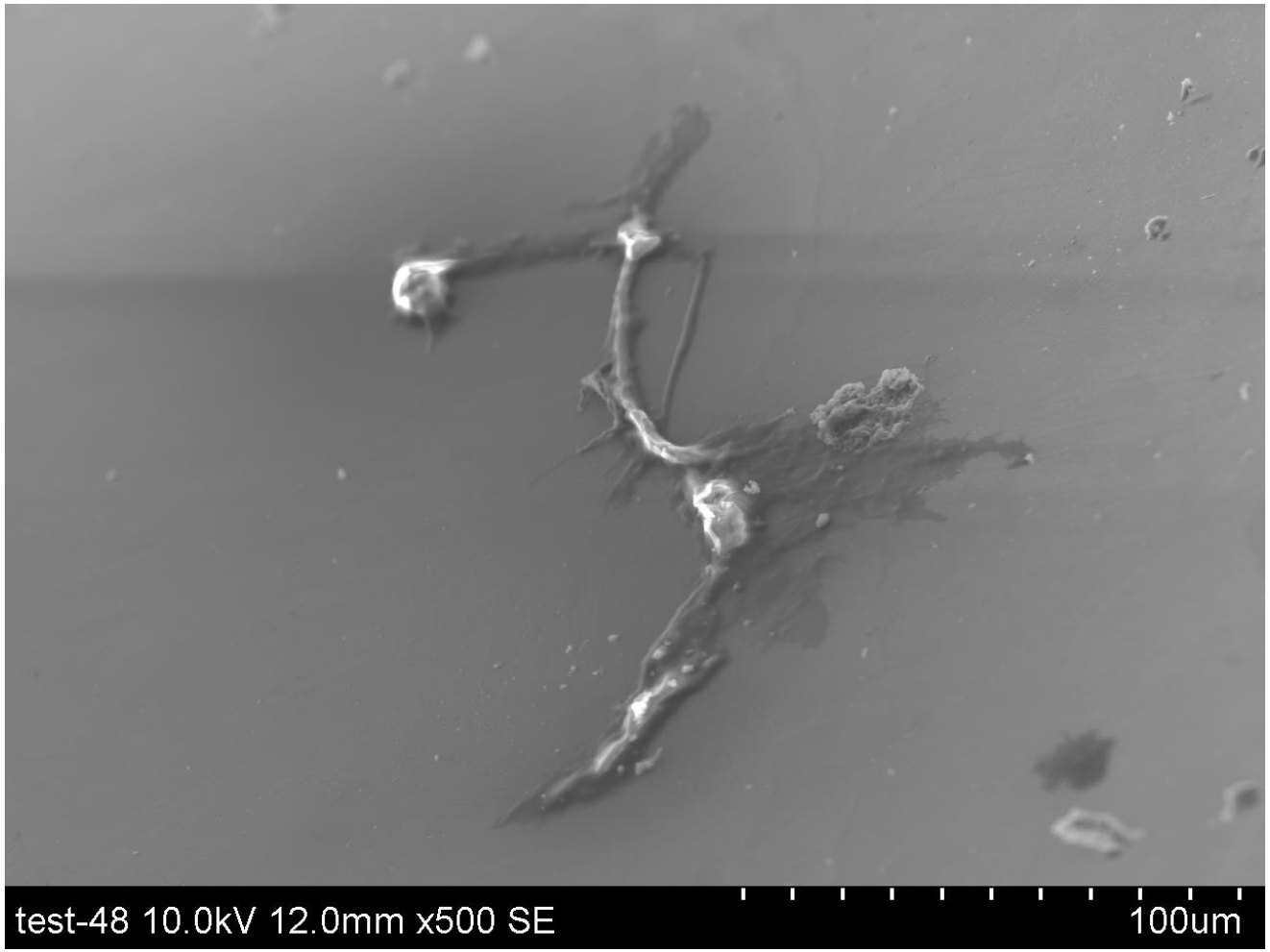
Control screw



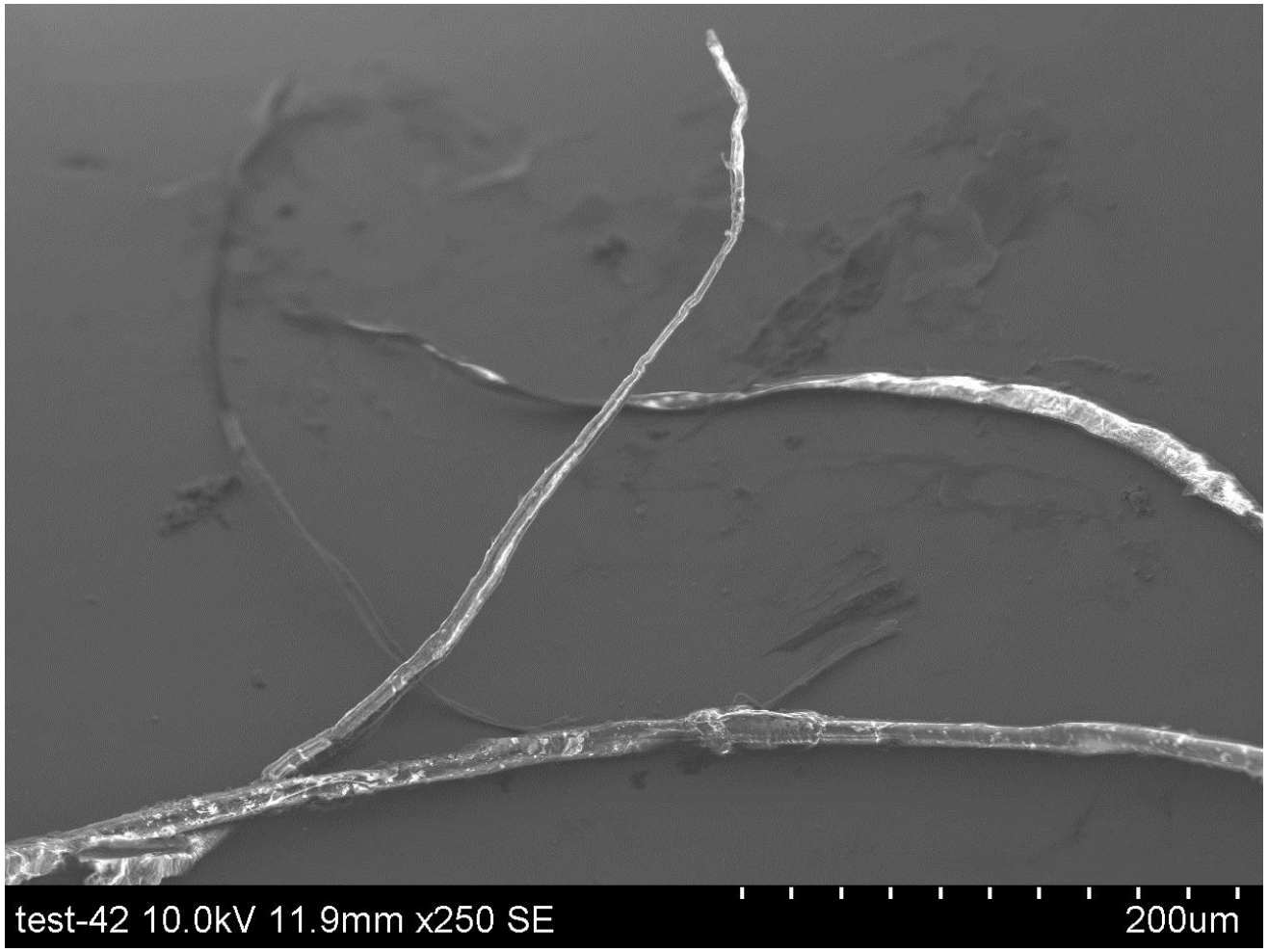
Reprocessed screw



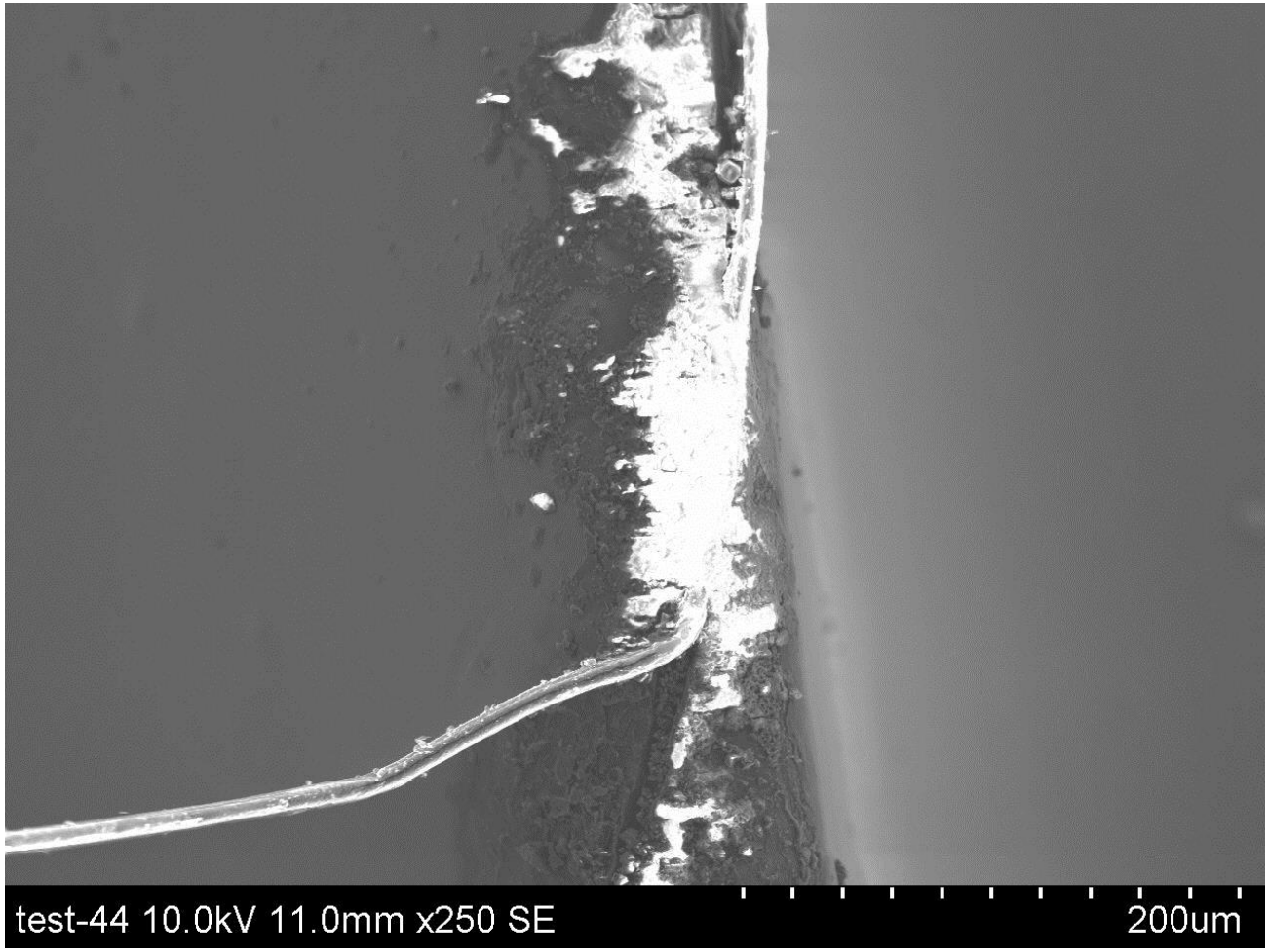
Reprocessed screw



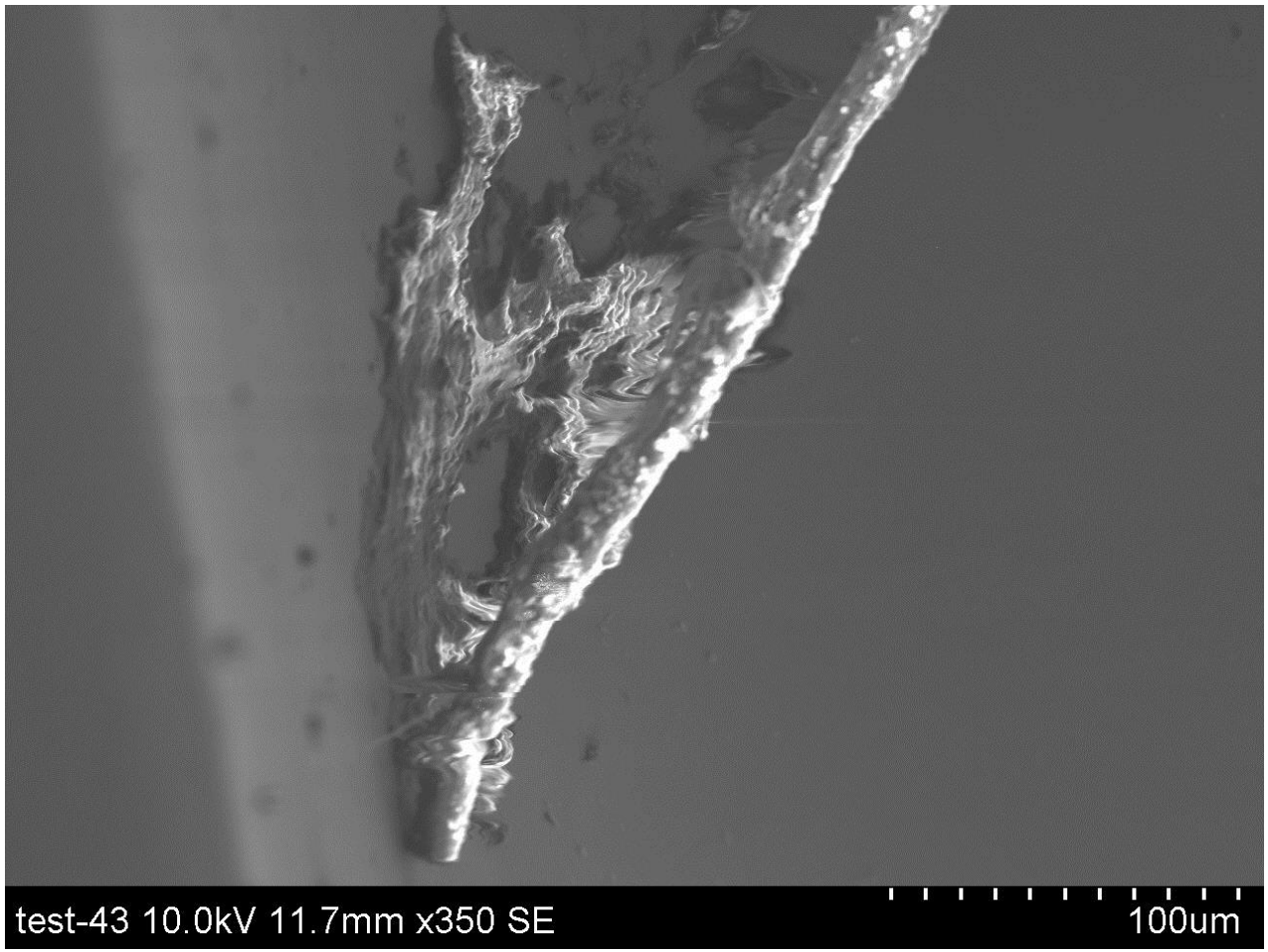
Reprocessed screw



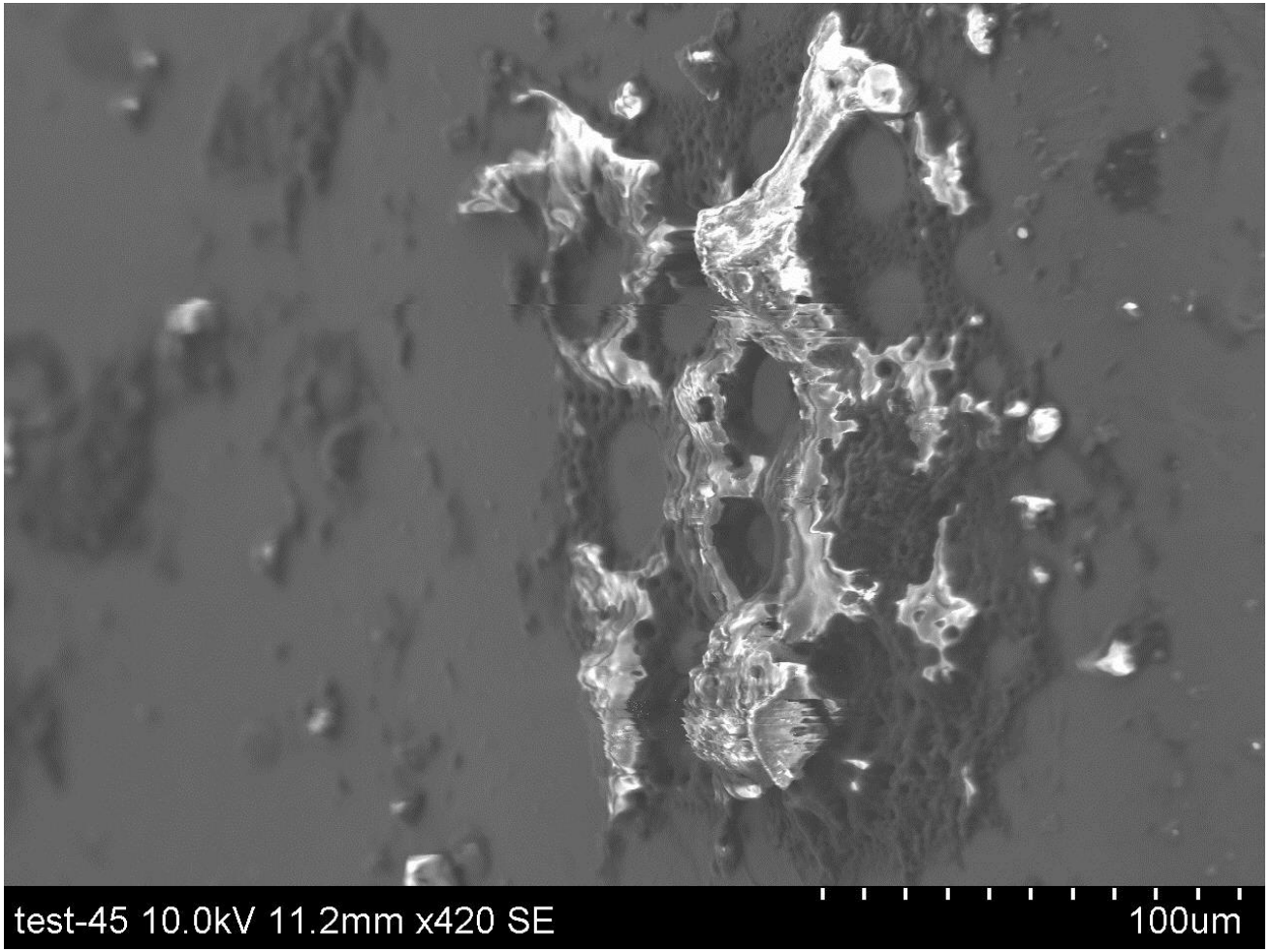
Reprocessed screw



Reprocessed screw



Reprocessed screw



Ramifications…

- Two possible implications of this research are that:
  - Small fragment sets and screw caddies may need to be redesigned to minimise the risks of fretting, galvanic, pitting and crevice corrosion of plates and screws and to facilitate effective cleaning and rinsing; and
  - Cleaning and sterilisation processes available in Australian SSDs may require improvement in order to:
    - effectively manage the impact of poor water and steam quality on reprocessing of plates and screws, as well as for all medical devices;
    - minimise the risks of damage occurring to stainless steel and other implant materials due to poor handling practices causing fretting corrosion and / or galvanic corrosion by processing similar metals together; and
    - ensuring the cleaning chemistries in use are appropriate for the application and used under carefully controlled conditions to ensure residues do not remain after processing.

Conclusion

- The results of this study provides:
  - Visual proof that screws in screw caddies show signs of contamination and corrosion
  - Evidence that exposure to an increased number of reprocessing cycles leads to increased rates of contamination, corrosion, deterioration and/ or damage
  - Impetus to change the common clinical practice in Australia from the routine use of screw caddies to individually packaged and sterilised plates and screws