



# Test Report – Implants Cleanliness



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Confidential for:  
Advanced Implants Inc.  
Daniel Bone  
Hip Drive 123  
48228 Detroit Michigan  
US

## Customer and test item

Customer:	Advanced Implants Inc.	Internal order No.:	Lab997-2012
Customer ID:	08/15	Internal sample-No.:	2012-EX-4633-1
Contact person:	Daniel Bone	Item description :	acetabular cup
Phone:	+1 (313) 445-4095	Sample-No.:	023
Street:	Hip Drive 123	Serial / Charge-No.	000001205026
Postcode::	48228 Detroit Michigan	Date of sample receipt:	02.01.12
Examiner :	M. Lankers	Exam date:	05.01.12

## Comment / Reason of investigation

Cleanliness testing according to ISO 16232 .

## Extraction

No. of components:	1	Method:	Ultra sonic
Weight / component:	135g	Ultrasonic duration:	5min
Surface / component:	360cm <sup>2</sup>	Filter type:	Cellulose nitrate
Solvent:	Water	Filter diameter:	47mm
Amount:	520ml	Pore size:	0.45µm

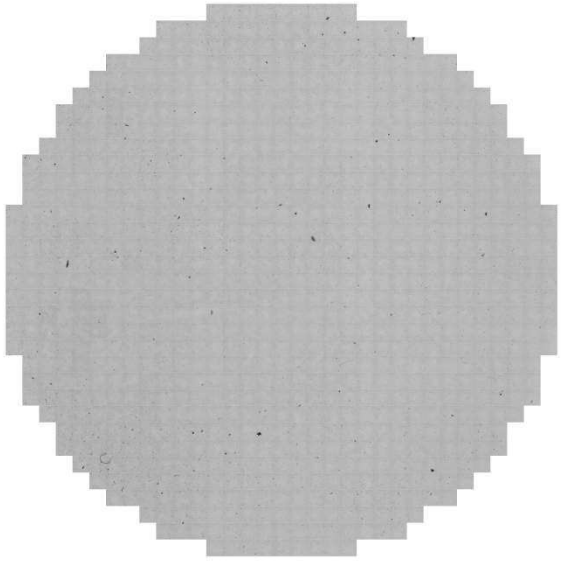
## Particle analysis

Device:	SPE 120-20 661110 (metal.ID)	Method:	LIBS
Field size:	1204.4µm x 1204.4µm (5x)	Resolving capacity:	1.0 Pixel / µm
	305.7µm x 305.7µm (39x)	Evaluation diameter:	40.95mm

## Summary investigation results

Largest metallic particle	Size:	375µm	Width:	47µm
Largest non-metallic particle <sup>1</sup>	Size:	225µm	Width:	214µm
Fibres <sup>2</sup> :	Largest fibre: Size:	173µm	Total length of fibre:	0.543mm
Wetted surface:	1,800cm <sup>2</sup>		Wetted volume:	2,600cm <sup>3</sup>
Gravimetric analysis:	n.a.		Requirements max.:	n.a.
CCC (without fibres):	A (B11/C10/D9/E7/F4/G3/H-K00)		CCC requirements:	A (B-D14/E10/F8/G6/H4/I-K0)
Blank value meets the requirements:	<input checked="" type="checkbox"/>		Component meets the requirements:	<input checked="" type="checkbox"/>



Particle overview			Filter overview
Particle size [µm]	Code	Amount	
5-15	B	812	
15-25	C	436	
25-50	D	234	
50-100	E	50	
100-150	F	17	
150-200	G	15	
200-400	H	7	
400-600	I	3	
600-1000	J	2	
> 1000	K	0	

Analysis results													
			Number	Size Distribution [µm]									
Results		Final Result	-	10-15	15-25	25-50	50-100	100-150	150-200	200-400	400-600	600-1000	>1000
metal.ID	raman.ID	Analyzed	50	0	0	6	3	17	15	7	3	2	0
Ti	Metal	Titanium	21	0	0	0	0	12	6	3	0	0	0
Organic	Polyethylene	Polyethylene	13	0	0	0	1	0	4	3	3	2	
Ca	Calcium-carbonate	Calcium-carbonate	5	0	0	5	0	0	2	1	0	0	0
Si, Na	Glass	Glass	3	0	0	1	0	0	2	0	0	0	0
Si	Quarz	Quarz	3	0	0	0	0	2	1	0	0	0	0
Cu	Metal	Copper	2	0	0	0	1	1	0	0	0	0	0
Fe, Cr	Metal	Steel High Alloy (Cr)	1	0	0	0	0	1	0	0	0	0	0
Fe	Metal	Steel Low Alloy	1	0	0	0	1	0	0	0	0	0	0
Ti	Titanium-oxide	Titanium-oxide	1	0	0	0	0	1	0	0	0	0	0
<b>Counting Result</b>			<b>1576</b>	<b>812</b>	<b>436</b>	<b>234</b>	<b>50</b>	<b>17</b>	<b>15</b>	<b>7</b>	<b>3</b>	<b>2</b>	<b>0</b>

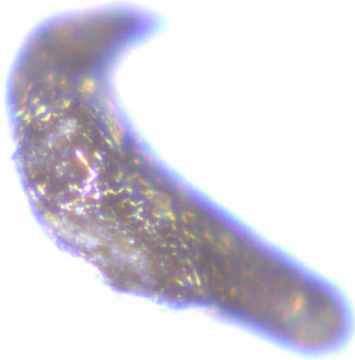
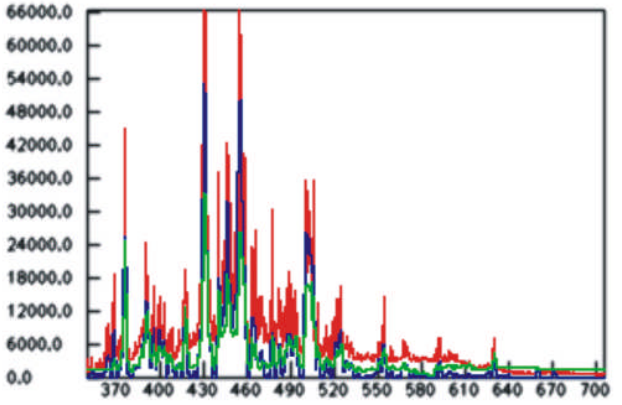
Report written by:  
Dr. Markus Lankers

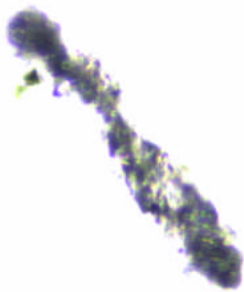
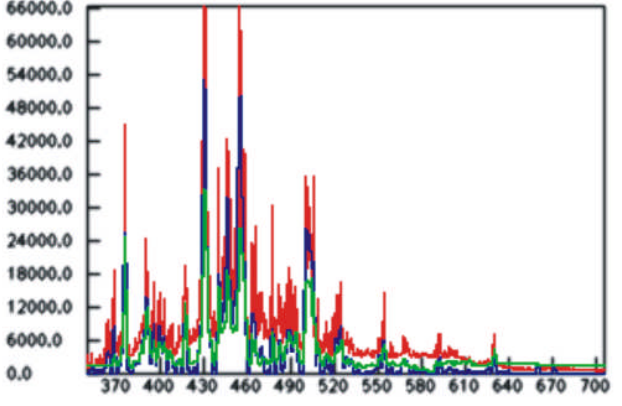
Report certified by:  
Dr. Oliver Valet

\_\_\_\_\_  
Date, Signature

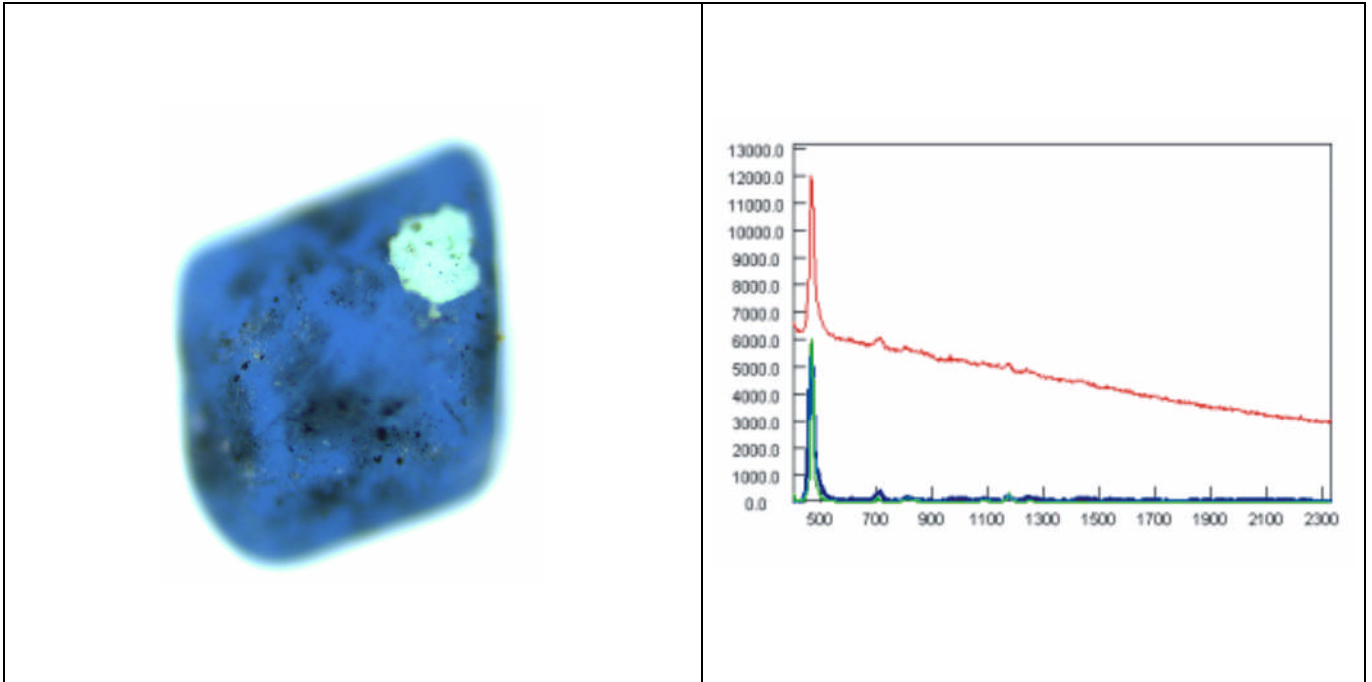
\_\_\_\_\_  
Date, Signature

**metal.ID (LIBS) - 1. largest particle, particle number 17.01**

 <p>50</p>	
<p><b>Granulometric result:</b></p> <p><b>Size x Width:</b> 375µm x 58µm  <b>Shape:</b> elongated  <b>Colour:</b> silvery</p>	<p><b>metal.ID (LIBS) result:</b></p> <p><b>Conformance:</b> Titanium  <b>Degree of conformance:</b> 98% - high  <b>Spectral quality (S/N):</b> 558 - good</p>

<p><b>metal.ID (LIBS) - 2. largest particle, particle number 43.01</b></p>	
	
<p><b>Granulometric result:</b></p> <p><b>Size x Width:</b> 271µm x 23µm  <b>Shape:</b> elongated  <b>Colour:</b> silvery</p>	<p><b>metal.ID (LIBS) result:</b></p> <p><b>Conformance:</b> Titanium  <b>Degree of conformance:</b> 93% - high  <b>Spectral quality (S/N):</b> 628 - good</p>

**metal.ID (LIBS) - 3. largest particle, particle number 53.01**



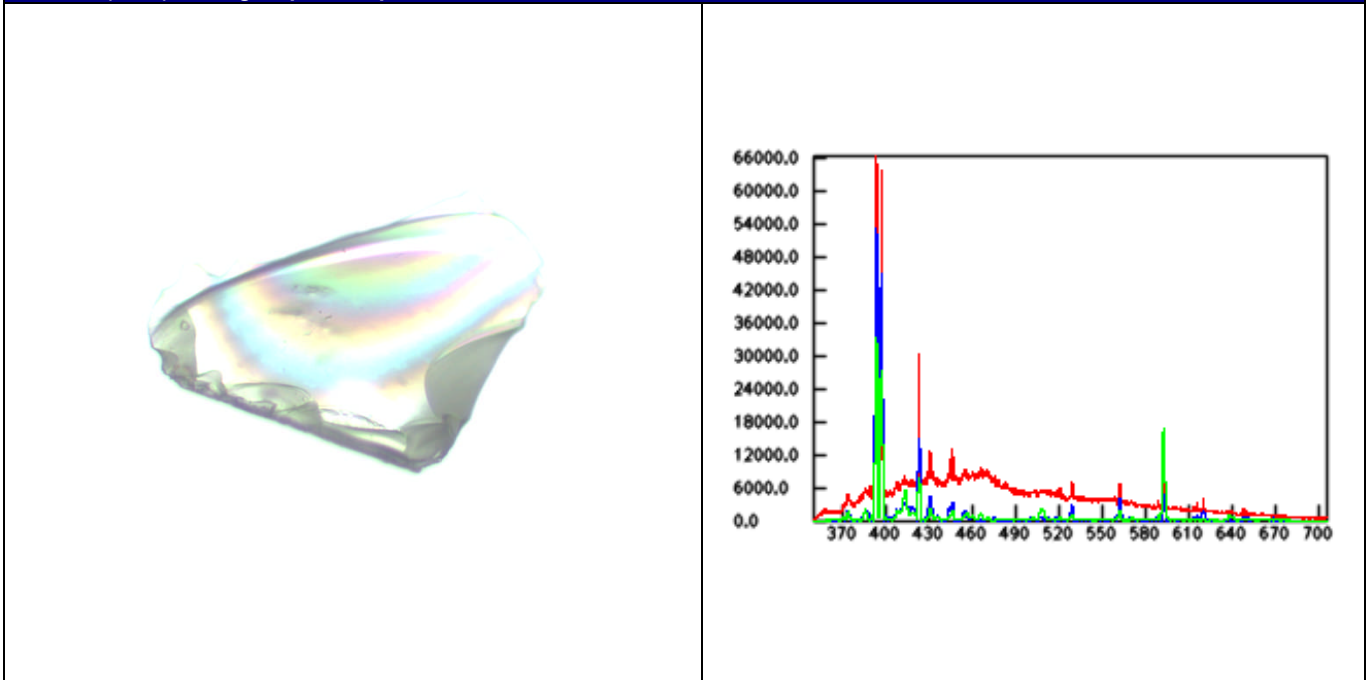
**Granulometric result:**

**Size x Width:** 225µm x 214µm  
**Shape:** compact  
**Colour:** blue

**raman.ID result:**

**Conformance:** Quartz  
**Degree of conformance:** 95% - high  
**Spectral quality (S/N):** 535 - good

**metal.ID (LIBS) - 4. largest particle, particle number 11.01**



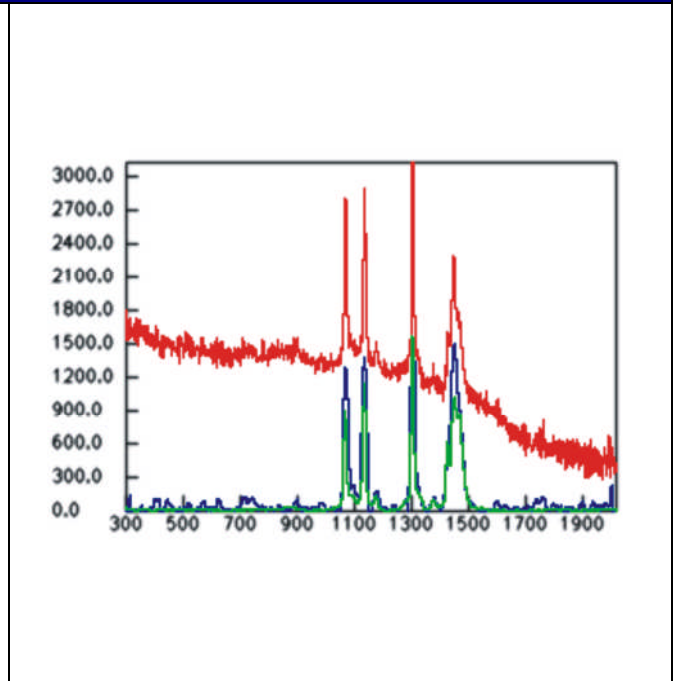
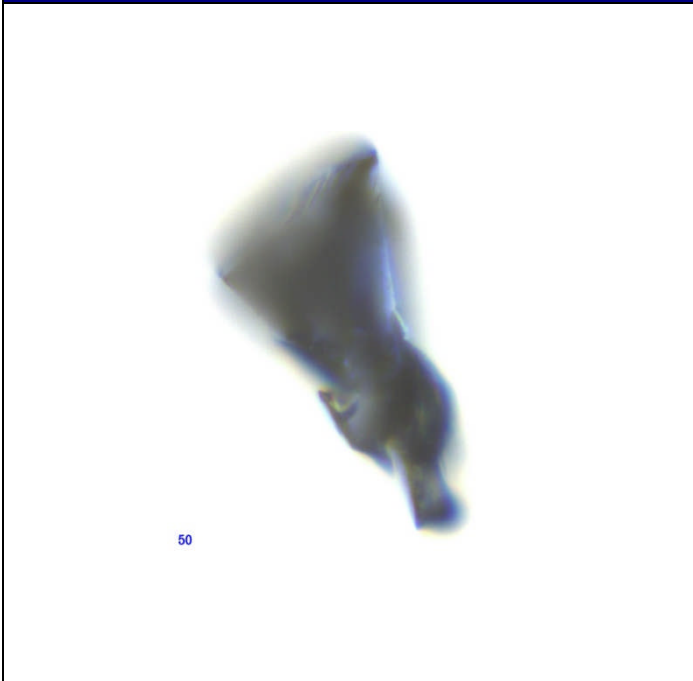
**Granulometric result:**

**Size x Width:** 215µm x 114µm  
**Shape:** triangular  
**Colour:** transparent, glassy

**metal.ID (LIBS) result:**

**Conformance:** Glass - Fiolax  
**Degree of conformance:** 93% - high  
**Spectral quality (S/N):** 435 - good

**metal.ID (LIBS) - 5. largest particle, particle number 38.01**



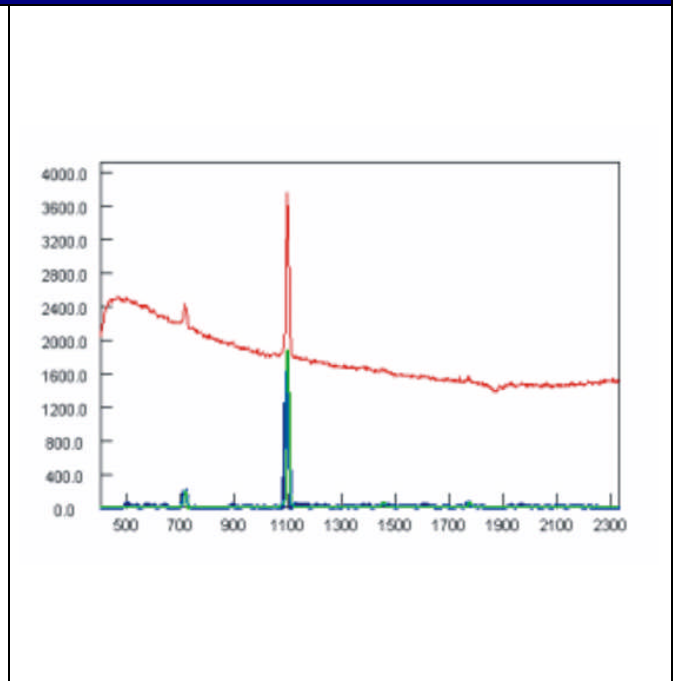
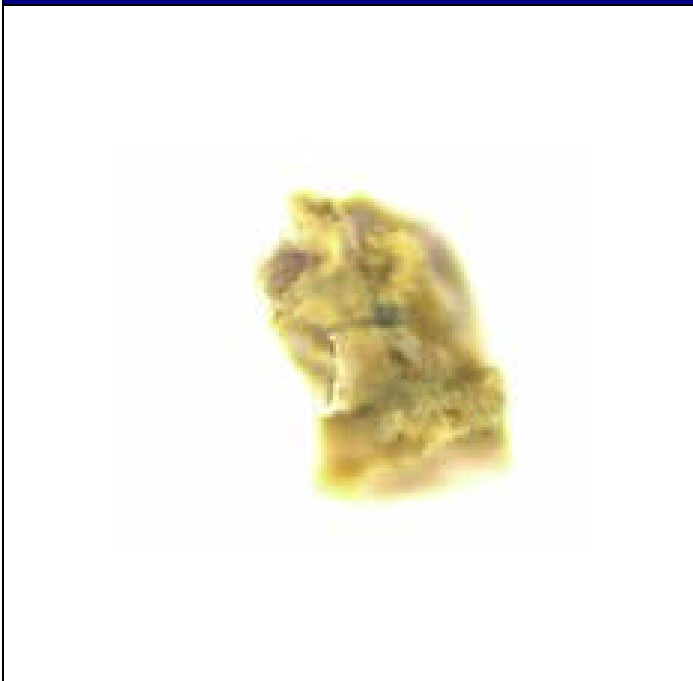
**Granulometric result:**

**Size x Width:** 191µm x 24µm  
**Shape:** elongated  
**Colour:** dark blue

**raman.ID result:**

**Conformance:** Polyethylene  
**Degree of conformance:** 90% - high  
**Spectral quality (S/N):** 335 - good

**metal.ID (LIBS) - 6. largest particle, particle number 17.02**



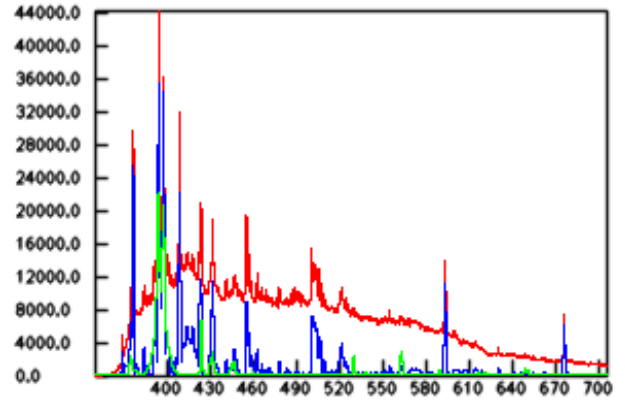
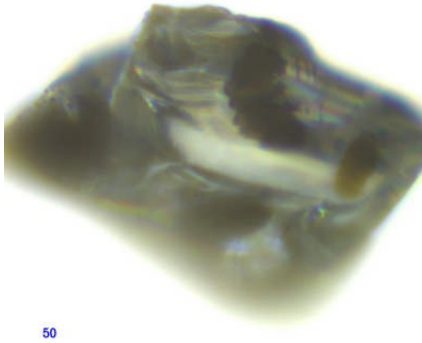
**Granulometric result:**

**Size x Width:** 185µm x 94µm  
**Shape:** compact  
**Colour:** yellow

**raman.ID result:**

**Conformance:** Calcium Carbonate  
**Degree of conformance:** 98% - high  
**Spectral quality (S/N):** 435 - good

**metal.ID (LIBS) - 7. largest particle, particle number 47.01**



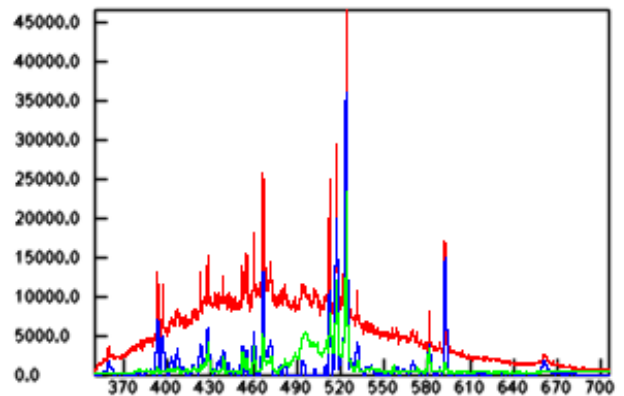
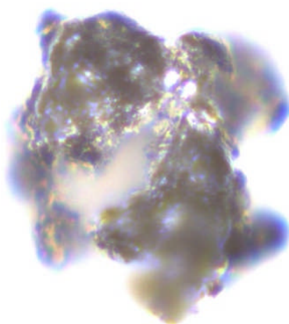
**Granulometric result:**

**Size x Width:** 175µm x 48µm  
**Shape:** compact  
**Colour:** brown

**metal.ID (LIBS) result:**

**Conformance:** Iron  
**Degree of conformance:** 88% - high  
**Spectral quality (S/N):** 335 - good

**metal.ID (LIBS) - 8. largest particle, particle number 54.01**



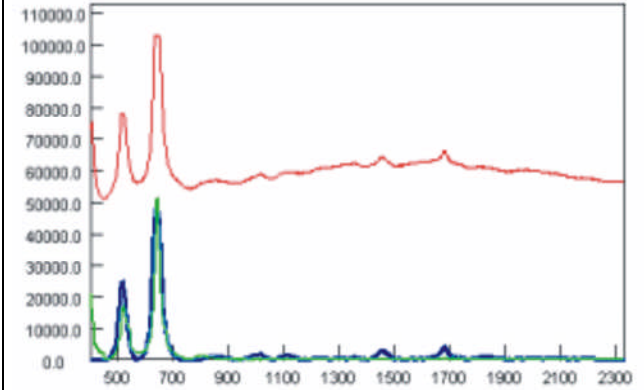
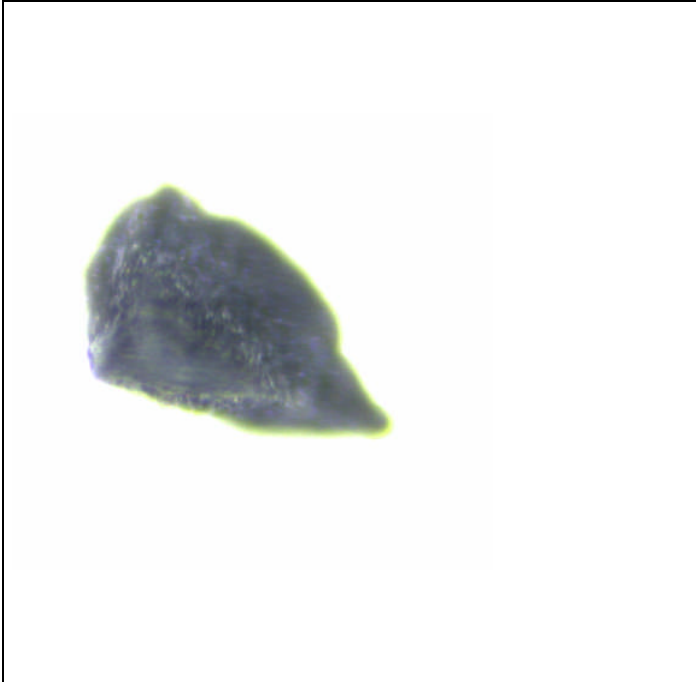
**Granulometric result:**

**Size x Width:** 170µm x 163µm  
**Shape:** compact  
**Colour:** silvery

**metal.ID (LIBS) result:**

**Conformance:** Copper  
**Degree of conformance:** 98% - high  
**Spectral quality (S/N):** 621 - good

**metal.ID (LIBS) - 9. largest particle, particle number 67.01**



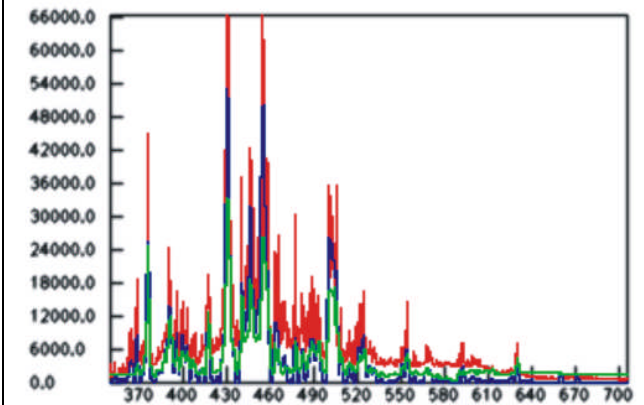
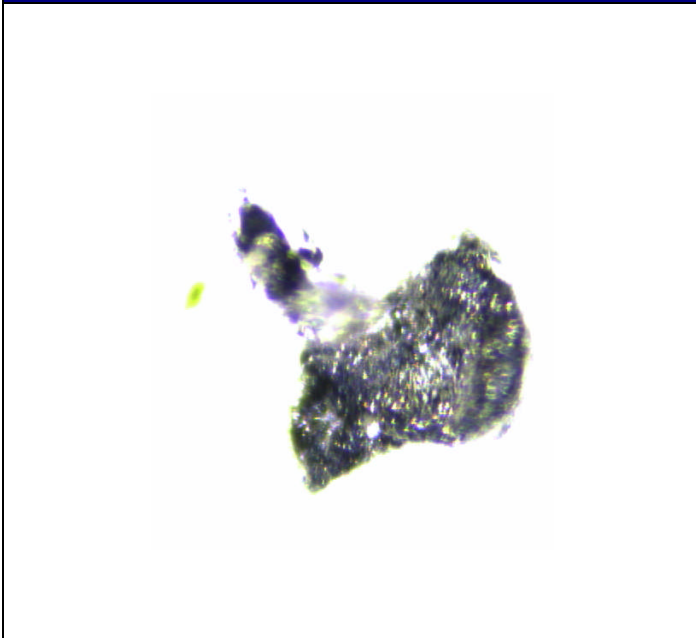
**Granulometric result:**

**Size x Width:** 164µm x 87µm  
**Shape:** compact  
**Colour:** anthracite

**raman.ID result:**

**Conformance:** Titanium Oxide  
**Degree of conformance:** 98% - high  
**Spectral quality (S/N):** 335 - good

**metal.ID (LIBS) - 10. largest particle, particle number 13.01**



**Granulometric result:**

**Size x Width:** 155µm x 144µm  
**Shape:** compact  
**Colour:** silvery

**metal.ID (LIBS) result:**

**Conformance:** Iron, Chromium  
**Degree of conformance:** 98% - high  
**Spectral quality (S/N):** 658 - good

1: non-metallic particles without fibres counted  
 2: definition fibre: compactness \* width / length > 20