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TECHNOLOGY ASSESSMENT VALIDATION UNIT - U.V.T.A.

Final Report
Second Phase

A NEW TECHNOLOGY FOR HIGHER STANDARDS IN REPROCESSING SURGICAL TOOLS AND M.D.

Customer:

BICARJET S.r.l. – Padua (Italy)

April 2013

Introduction

Reprocessing reusable surgical tools is one of the most critical procedures for patients and operators safety because of the high biological risks involved.

There is a high economic cost for hospitals associated with the process of sterilizing medical devices.

The standard sanitation/sterilization process is special in the sense its end result cannot be verified by subsequently testing the medical devices. Thus, the only guarantee to correct sterilization is by completing the process meticulously, according to the stages below:

- Collection
- Decontamination
- Washing
- Rinsing and drying
- Checking and maintaining instrument
- Packaging
- Sterilization
- Traceability
- Checking and validation

The first stages of gathering, decontamination and cleaning of material are not directly related to the process of sterilization as the presence of organic residue may affect the final sterilization result (sterilized product as defined by Community Law UNI EN-556-1).

Organic residue is removed following standard procedures and involves:

- submersion in an enzymatic solution. When choosing the fixative, one must take into account its effectiveness in relation to the primary cleaning purpose and how it compares to other biological agents;

- manual brushing if there is still presence of organic residue;
- ultrasound cleaning cycle. This will remove any solidified organic residue on components based on the principle of ultrawaves cavitations;
- Rinsing.

Manual brushing is considered a core standard but it subjects operators to a high biological risk. Hence, alternatively or additionally to manual brushing, the medical instrument can be inserted in the Technology proposed by BICARJET® S.r.l.. The technology's challenge is to overcome the limits and critical aspects brought to light by current procedures since it is able to remove and reduce injuries caused by manually brushing components. This is in light of the fact that sterilization entails the complete removal of organic residues on surfaces.

Assumptions

The World Health Organisation (WHO) has proposed a number of short-, medium- and long-term policies to minimize the risks involved when dealing with or managing potentially contaminated material so as to safeguard the operator's health and safety. This reprocessing cycle also guarantees a total absence of pathogenic micro-organisms that may cause functional, immunological, toxicological and health complications in patients.

Thus, it is essential to remove all organic residue as the sterilization process does not guarantee complete removal of micro-organisms that can adhere to the surface of the instrument. This is critical for medical devices and/or surgical instruments used for diagnostic or therapeutic purposes and as categorized by Ministerial Decree as instruments requiring cleaning and sterilization (instruments that come in contact with blood, areas of the body that should be kept sterile and mucous (Spaulding Classification, 1977).

A major concern is the system by which the process of cleaning surgical tools is certified. The review of literature and current decontamination alternatives has brought this to light without, however, offering a solution (Different experimental protocols for decontamination affect the cleaning of medical devices. A preliminary electron microscopy analysis; Tessarolo et al. 2006).

A similar study observing and investigating the limitations of the standard certified cleaning processes of surgical instruments used in large hospitals has not provided a guarantee for its effectiveness.

Pilot survey: preliminary data and results

The pilot study on the BICARJET® S.r.l. technology was able to conclude that the technology proposed cleans in depth and evidently removes organic residue on the surgical instruments examined. This data is supported by Dino-Light microscope images (magnification of up to 500X) and confirmed by a Scanning Electron Microscope (SEM). After normal usage and cleaning with the BICARJET® technology, no macroscopic or microscopic residues were found on the surface of the instrument. Moreover, the technology does not seem to be affected by the shape of the instrument or post-usage storage time (tested between 0 and 15 days).

The characteristics of the process were developed in terms of pressure, distance, duration, nozzle type and bicarbonate based on the results obtained. These were then used to standardise the mechanical cleaning parameters inside the COMPACT900 cabinet:

- Bicarbonate type MELTRON® GG
- MINIJET nozzle
- Outlet pressure 3 BAR
- 5 - 10 cm distance from the instrument
- Exposure to bicarbonate about 30 seconds
- Final rinse.

Targets

In view of the results obtained in the pilot study, the primary target of this study is to evaluate the effectiveness and efficiency of the Technology proposed by BICARJET® S.r.l. in removing organic residue from surgical instruments. It will compare this to current cleaning standards used in accredited sterilisation processes considered safe

for the operator and the patient, and pose minimum biological risks for the reuse of instruments.

The secondary target is to evaluate the effectiveness and efficiency of the technology proposed by BICARJET® S.r.l. in removing organic residue from surgical instruments under high stress (meaning used continuously far longer than normal clinical practice). The study will then look at how this compares to cleaning instruments used according to normal clinical practice by BICARJET® S.r.l.'s proposed technology. Finally, it will identify the system's efficiency in removing residue.

Materials and methods

Statistical Units comprising medical devices

Currently reprocessed medical devices, categorized under Directive 93/42/CEE and its subsequent modifications according to their risk class, include those of high risk of biological contamination.

The reprocessing methods used must guarantee the instruments' safety, in terms of material and functionality, as if they were new (DIN EN ISO 1348:2003).

Definition of Representative Sample and Quantity

The sample of medical devices taken for this study pertain to the surgical instruments used by the U.O. of the Neurosurgical Department.

Specifically, stainless steel surgical bone drills used to perforate bone structures that enclose the central nervous system.

The reusable osteotomy surgical drills have been selected based on their frequency of use in the various Surgical Units:

- CRANIOTOME BURR GE520R;
- ROSEN BURR GE407R;
- DIAMOND BURR GE517R.

The sample comprises 29 reusable surgical burrs which were selected based on their frequency of use at the *Azienda Ospedaliera di Padova*:

- 10 **Craniotome**, of which 7 were taken from the Neurosurgical Unit and used for skull perforations, 2 were used on connective tissue of the skull to increase tissue adherence on surface and a new one used for reference purposes.

- 11 Rosen Burr GE407R (4 mm stainless steel), of which 8 were used in surgery by the Neurosurgery Unit, 2 were used on connective tissue of the skull to increase tissue adherence on surface and a new one used for reference purposes.

- 8 Diamond Burrs GE517R (hardened steel with diamond coating) of which 5 were used in Neurosurgery, 2 on connective tissue of the skull to increase tissue adherence on surface and a new one used for reference purposes.

Method definition

Stratified sampling by devices' dimensions and morphological characteristics.

Stratified sampling by Operational Unit.

Proportionate stratified sampling by frequency of use.

These sampling strata have been chosen based on the variables.

This stratified sampling design was chosen based on variables that may affect the result. These are the morphological characteristics and tissue type, both of which are independent variables.

Technology definition

A. Standard Technology for decontamination and Sterilization

The reprocessing protocol provides for:

- Ordinary use in S.O.
- Instrument decontamination on sight
- Soaking in an enzymatic solution
- Manual brushing of the said instrument to remove any organic residue
- Immersion in an ultrasonic machine (0.5% dilution, for 5 minutes at a temperature of 30°C)
- Rinsing
- Thermodisinfection
- Sterilization

B. Innovative Tetchnology BICARJET® S.r.l.

The technology consists in cleaning surgical instruments with a jet of sodium bicarbonate, emitted at low pressure by compressed air, ensuring surfaces are cleaned thoroughly and effectively. This process substitutes manual brushing, the latter having been proven ineffective due to the complex surfaces and dimensions of surgical tools as well as a result of human error.

On the other hand, sodium bicarbonate salts, of which size can vary between 500 and 50 µm, strike the surfaces uniformly and continuously, hence reaching deep in interstices and removing contaminants from surfaces. The mechanical process does not abrade the surface of the material since the salt dissolves as a result of the kinetic energy used during the cleaning action itself. Sodium bicarbonate does not corrode surfaces, is 100% biodegradable is non-toxic to the environment, and most importantly not dangerous for operators.

This technology proposes to resolve any clinical doubts on the cleaning of reusable surgical instruments, which often leads to these being used as disposable instruments.

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This compound is distributed by means of compressed air through the cleaning system "SOBIJET®" (see Fig 1.). This consists of a compact cabinet called "Compact 900", part of the innovative technology proposed by BICARJET® S.r.l.. Its dimensions have been easily adapted to meet logistical requirements of the plant areas without disturbing their day-to-day activities.

The cabin is made of thick stainless steel INOX AISI 304 with a side loading door and hook locks, a window featuring tempered glass and a pneumatic wiper and external lighting. The operator's post is equipped with latex gloves and two jet hoses emitting MELTRON®. Two different jets are available to distribute the MELTRON® solution (Microjet and Minjet), depending on the degree of precision required. An externally positioned compressed air gun removes any remaining bicarbonate residues from surfaces. The system is connected to a feeding unit operated via a pneumatic remote pedal control. The unit consists of a discharging hopper and a MELTRON® solution double Venturi "HPV" dosing system developed and patented by BICARJET® S.r.l..

A flexible hose, used for suction purposes, securely connects the cabin with the cyclone dust collector. Other technical parts are available to the standard COMPACT900 cabin.

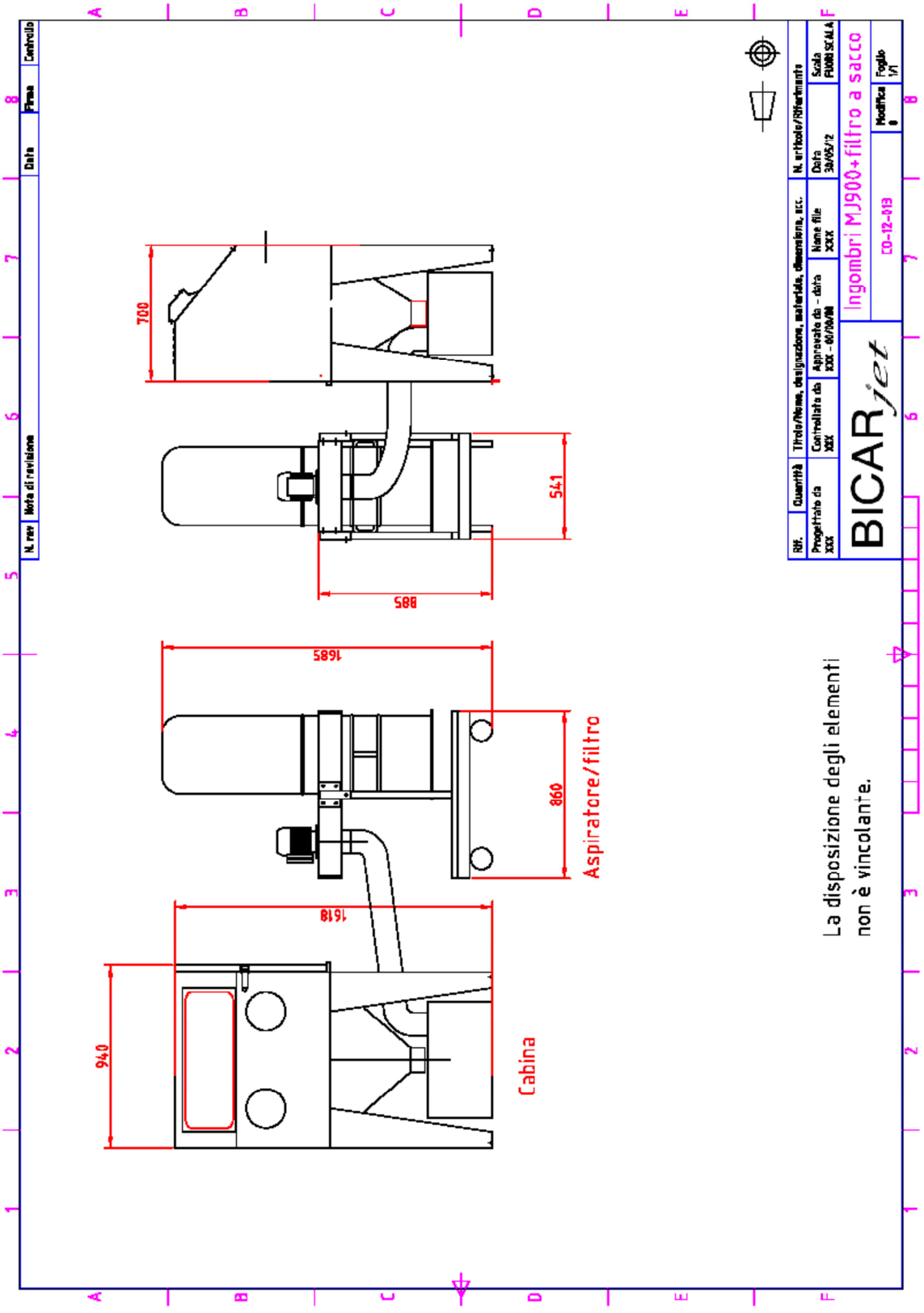


Fig 1. Compact 900: a compact cleaning system

C. Scanning Electron Microscope Technology

Samples where further analysed using an electron microscope (SEM).

Electron microscopy, in fact, is an invaluable tool in evaluating disinfection, cleaning and sterilization protocols for reusable tools.

The samples were fixed in Karnovsky solution (4% paraformaldehyde + 2.5% phosphate buffered glutaraldehyde of 0,1M, pH 7.2) for two hours, left to dehydrate in ethyl alcohol and later in CO_2 following the Critical Point Drying technique. Samples were mounted on aluminium, observed and photographed with a scanning electron microscope (ESEM FEI, Holland). An EDX probe was used to analyse particles found on the samples to identify their chemical composition.

The data collected included the number of particles found in the sample and the area of the sample they covered in relation to the sample's total area. This was done through a computerized morphometric analysis (Image PRO-PLUS, Media Cybernetics, Maryland, USA).

Study Design

Controlled prospective study.

The proposed study will evaluate the ability to remove biological residue from reusable medical devices. Electron microscopy and digital imaging will be used to quantify any biological residue.

The study is concerned with the day to day usage of surgical instruments. It will serve to quantify the effectiveness of MELTRON® solution as a cleaning agent as well as to compare it to other standard decontamination and sterilization processes.

The second part of the study aims to establish the effectiveness of the MELTRON® solution on burrs used on connective tissue of the skull in order to attain higher tissue adherence.

Thus, 29 samples were selected and analysed as explained below:

- 3 burrs, one of each type, taken from the Hospital Unit – Neurosurgical department after being used as per standard clinical procedures. These were

stored individually in sterile test tubes, preventing any type of external contamination and decontaminated using the following standard method:

1. Soaking in an enzymatic solution
2. Manual brushing of the said instrument
3. Immersion in an ultrasonic machine (0.5% dilution, for 5 minutes at a temperature of 30°C)
4. Rinsing

- 6 burrs, 2 of each type, used in simulated craniotomies. These were subjected to a higher than normal rate of usage in terms of time and extended cutting. This increased the adhesion of protein residue bringing the instrument at a critical temperature as evidenced by the loss of organic thread.

- The remaining burrs, taken from the Neurosurgery department after being used as per standard clinical procedures, and the 3 stressed burrs were cleaned following the protocol tested in the preliminary phase of the study. Standard protocol entails:
  - Normal use;
  - Storage of instruments by Operational Unit personnel in sterile test tubes to prevent any type of external contamination.
  - Recovery of instruments from test tube, application of identifying data and data collection based on the origin and type of sample respectively;
  - Once on the manual cleaning site, the instrument was extracted from the test tube, even after being held 15 days in storage, and then treated as follows:
    - Photographed with a digital photographic camera, Nikon D300.
    - Scanned and photographed with a digital microscope Dino Light, magnification at 500X.

- Mechanically cleaned with a MELTRON® solution inside the compact cabinet described above.
- Scanned and photographed further with a digital microscope Dino Light, magnification at 500X.
- Clean instrument stored in a new sterile test tube plus identification applied depending on the specimen and process submitted to.

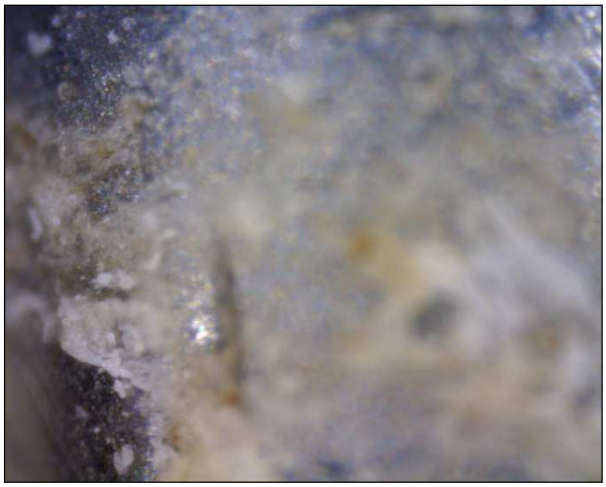
Results

Craniotome GE520R

CS1: Stressed Sample

- Used on anatomical tissue (Skull Bone) in autopsy room
- 3:07 minutes of continuous cutting on a 5 x 3 cm surface

Before



Cleaning:
30 seconds exposure to MELTRON® GG
Pressure 3 bar - Distance 5 - 10 cm – Rinsing and Blowing

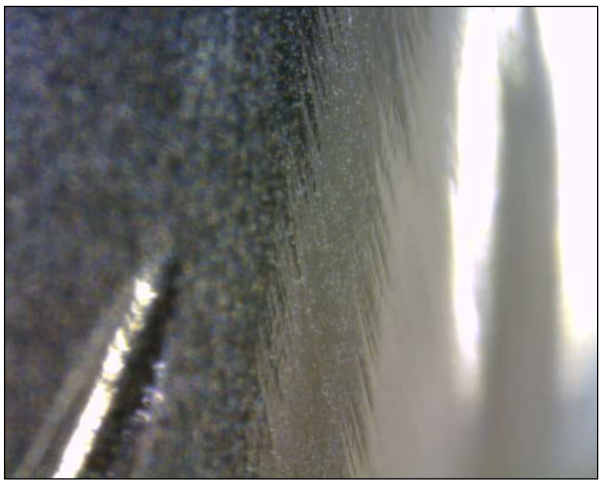
30 seconds exposure to MELTRON® GG
Pressure 3 bar - Distance 5 - 10 cm – Rinsing and Blowing

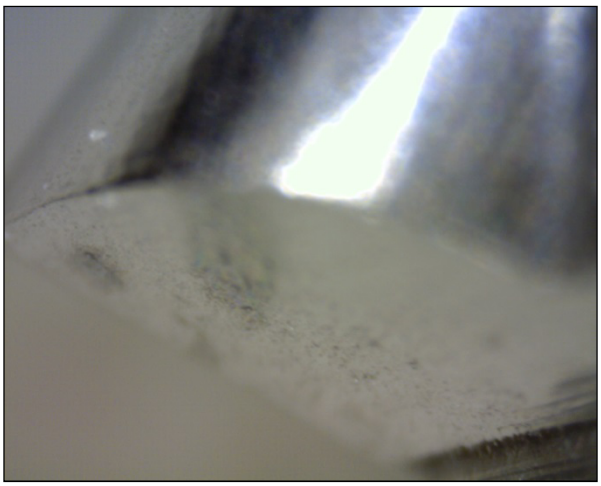
Machine Inspection:
During the first few tests a malfunction occurred inside the cabin resulting in an inefficient cleaning process; the test was repeated after troubleshooting.

Cleaning:
40 seconds exposure to MELTRON® GG
Pressure 3 bar - Distance 5 - 10 cm – Rinsing and Blowing

10 seconds exposure to MELTRON® GG
Pressure 3 bar - Distance 5 - 10 cm – Rinsing and Blowing

After

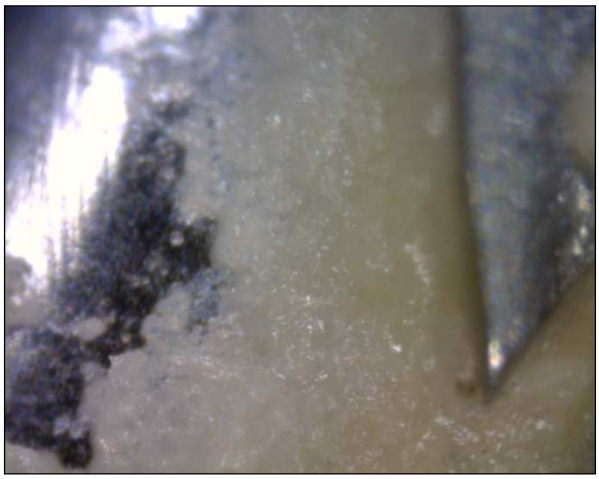




CS4: Stressed Sample

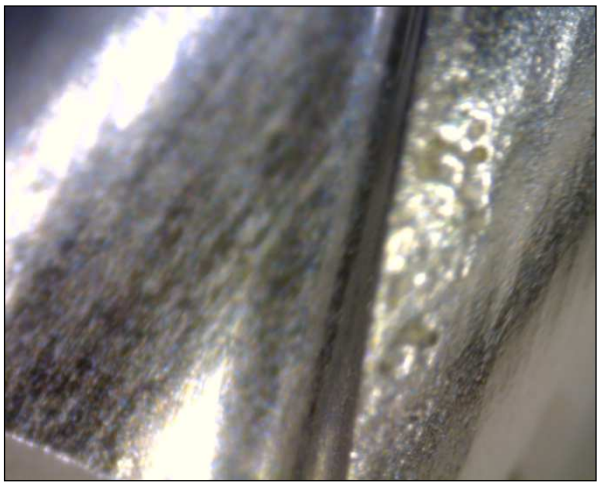
- Used on anatomical tissue (Skull Bone) in autopsy room
- 4:51 minutes of continuous cutting on a 5 x 10 cm surface

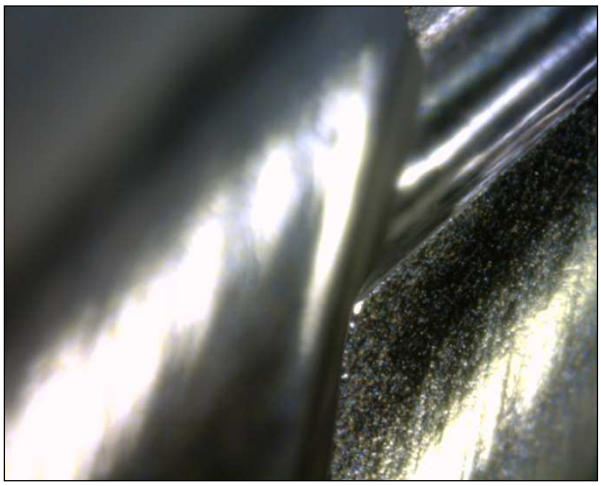
Before



Cleaning:
45 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

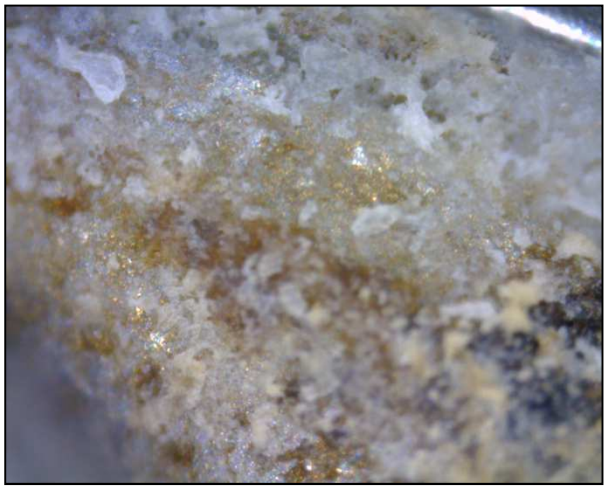
After





C7: Sample taken after standard use at the Neurosurgical Department (craniotomy)

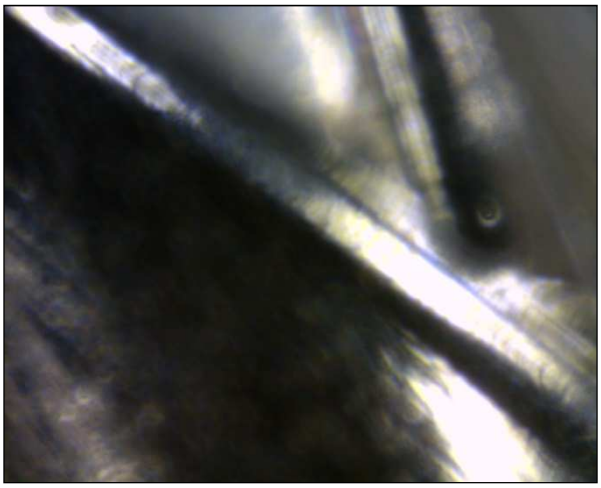
Before



Cleaning:
30 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

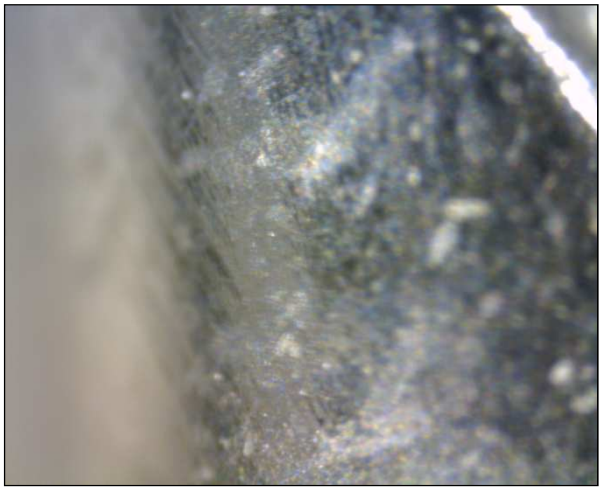
30 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

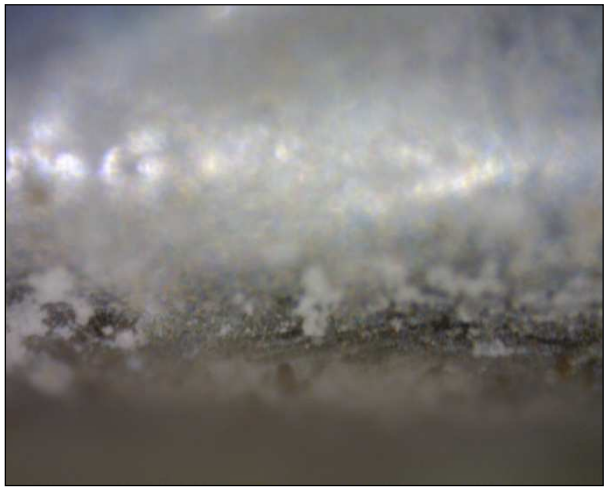
After



C11: **S**ample taken after standard use at the Neurosurgical Department (craniotomy)

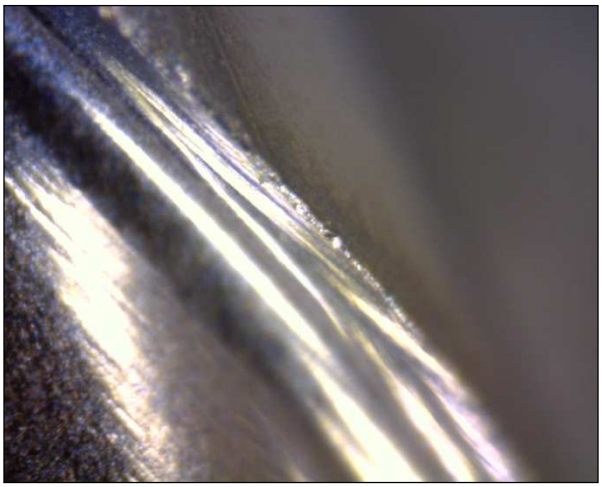
Before





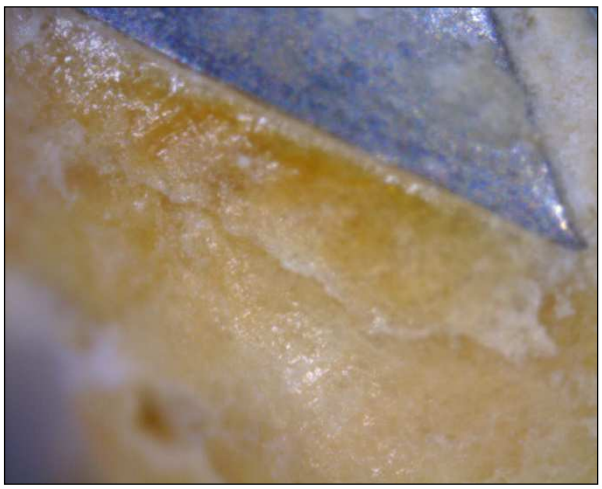
Cleaning:
30 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

After



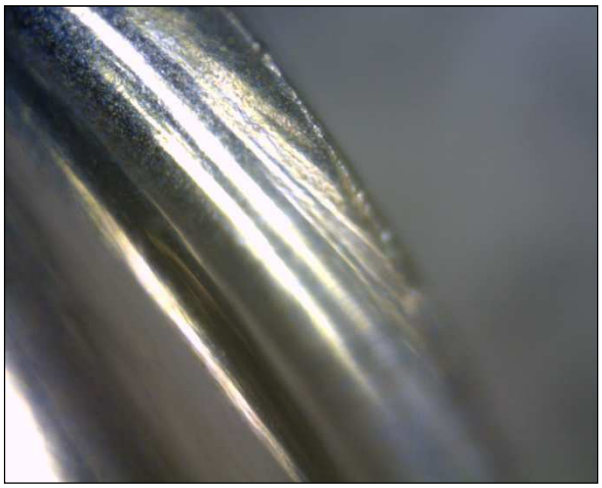
C18: Sample taken after standard use at the Neurosurgical Department (craniotomy)

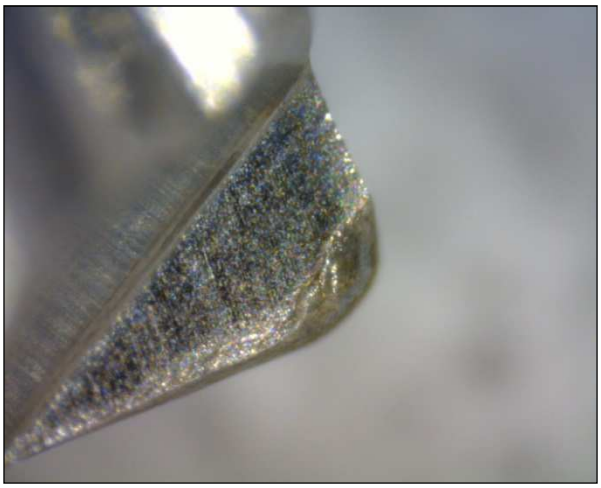
Before



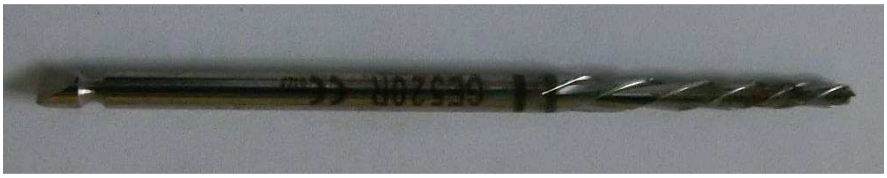
Cleaning:
60 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

After





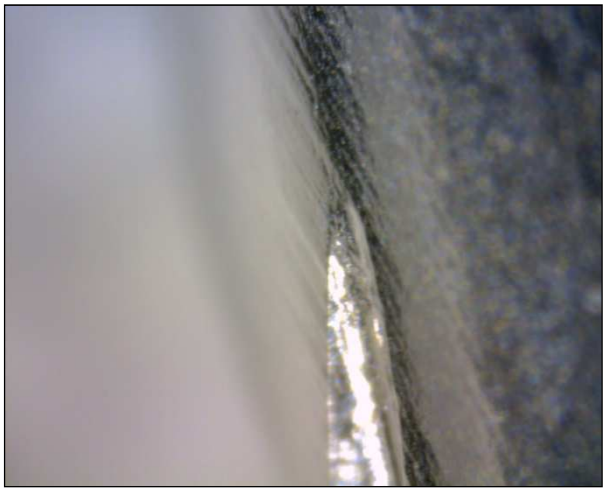
C19: Sample taken after standard use at the Neurosurgical Department (craniotomy)

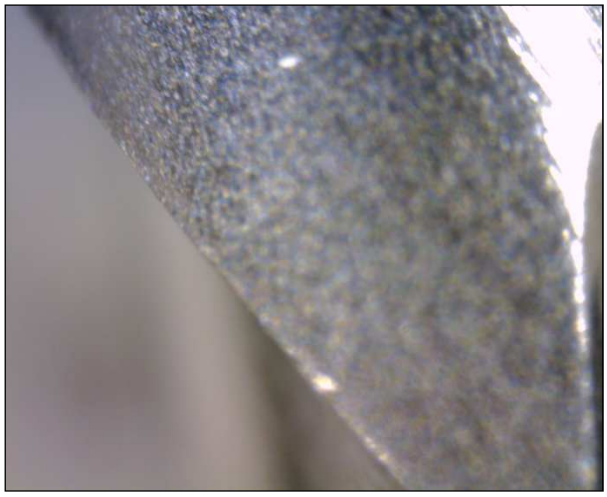


Before

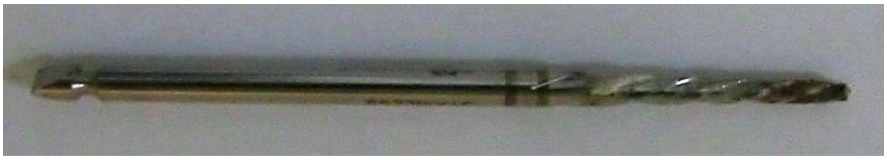
Cleaning:
60 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

After





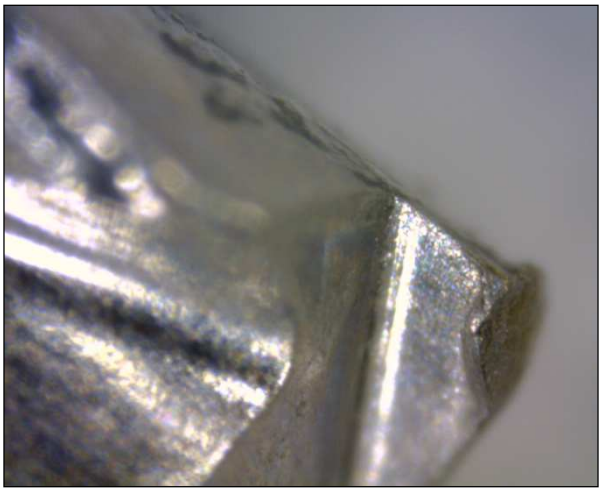
C20: Sample taken after standard use at the Neurosurgical Department (craniotomy)



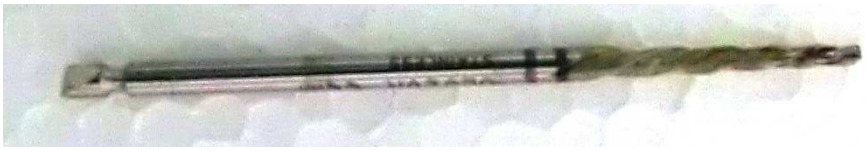
Before

Cleaning:
60 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

After



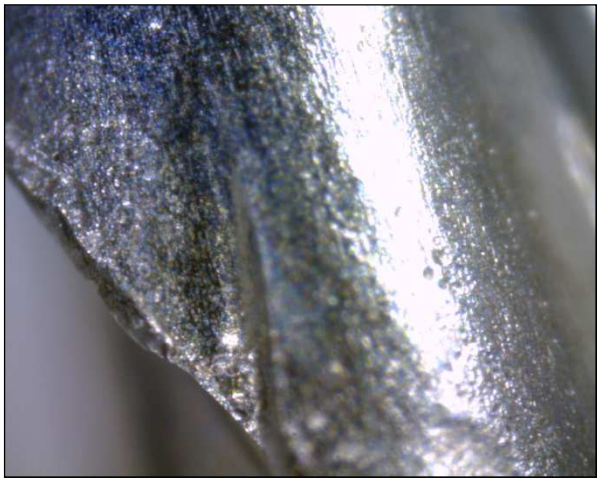
C23: Sample taken after standard use at the Neurosurgical Department (craniotomy)

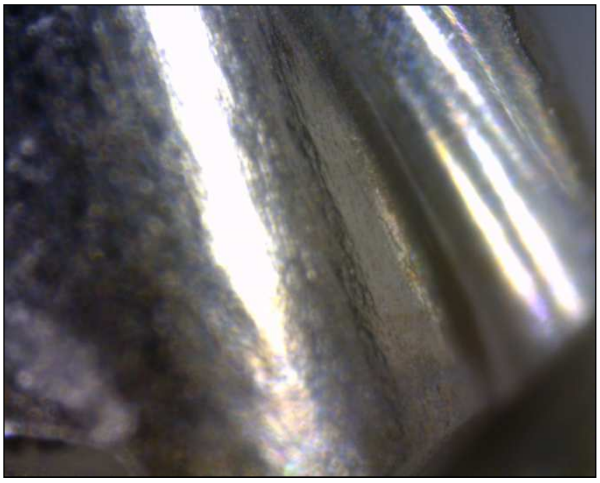


Before

Cleaning:
40 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

After





CP25: Standard monitoring cycle of model under study taken from the Neurosurgical Department after normal clinical practice (craniotomy).

Cleaning:
Standard decontamination process which entails:

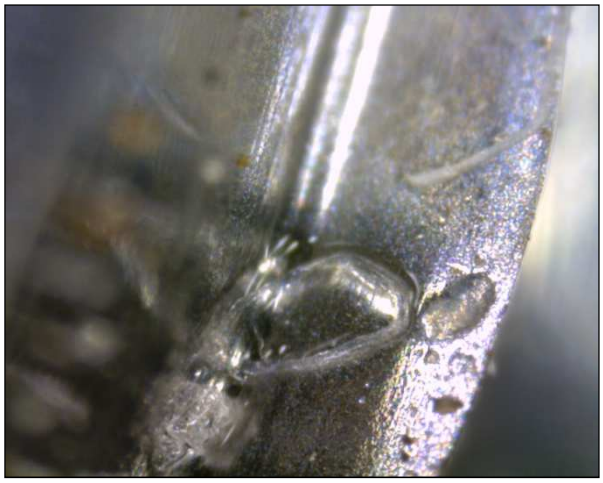
1. Soaking in enzymatic liquid
2. Manual brushing of the said instrument
3. Immersion in an ultrasonic machine (0.5% dilution, for 5 minutes at a temperature of 30°C)
4. Rinsing

Rosen Burr GE407R

RS2: Stressed Sample

- Used on anatomical tissue (Skull Bone) in autopsy room
- 3:26 minutes of continuous milling on a 5 x 3 cm surface

Before



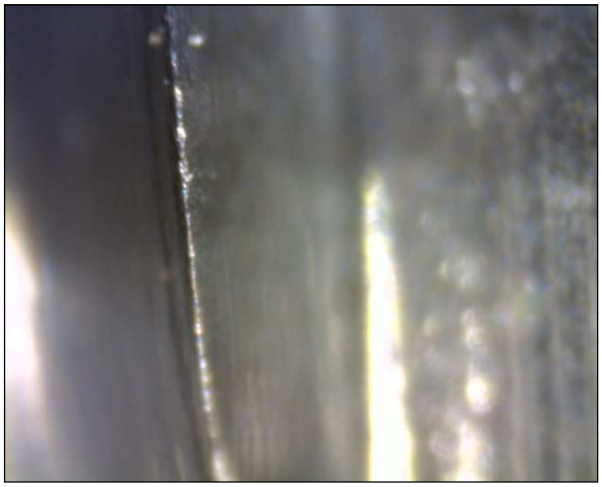
Cleaning:
30 seconds exposure to MELTRON® GG
Pressure 3 bar - Distance 5 - 10 cm – Rinsing and Blowing

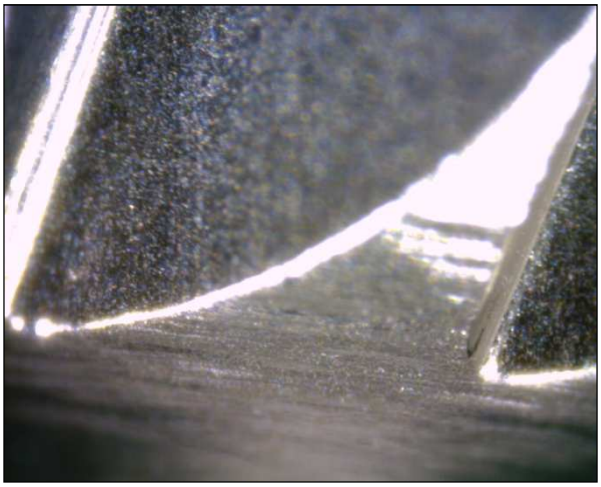
0 second exposure to MELTRON® GG
Pressure 3 bar - Distance 5 - 10 cm – Rinsing and Blowing

Machine Inspection:
During the first few tests a malfunction occurred inside the cabin resulting in an inefficient cleaning process; the test was repeated after troubleshooting.

Cleaning:
40 seconds exposure to MELTRON® GG
Pressure 3 bar - Distance 5 - 10 cm – Rinsing and Blowing

After

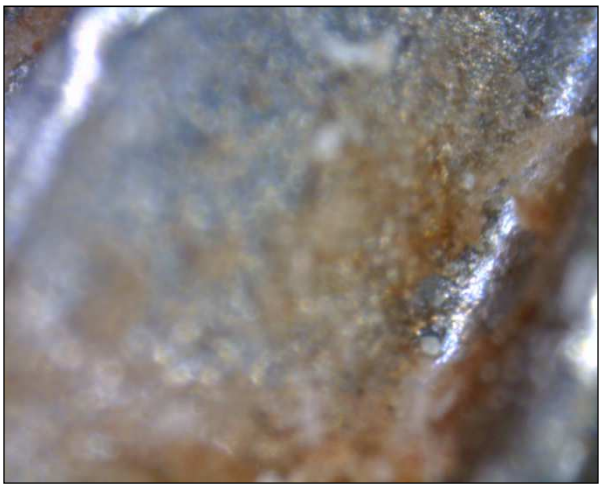




RS5: Stressed Sample

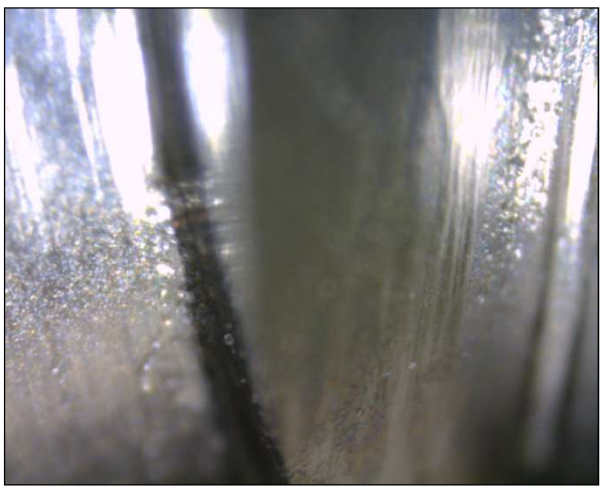
- Used on anatomical tissue (Skull Bone) in autopsy room
- 5:12 minutes of continuous milling on a 5 x 10 cm surface

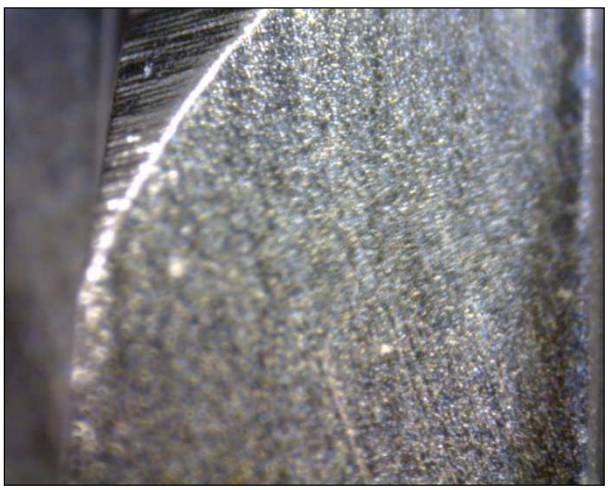
Before



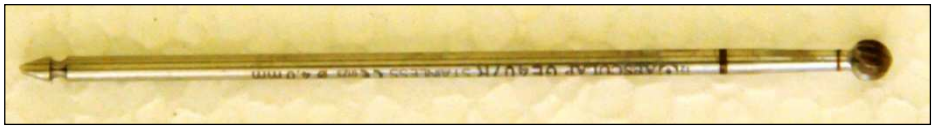
Cleaning:
50 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

After

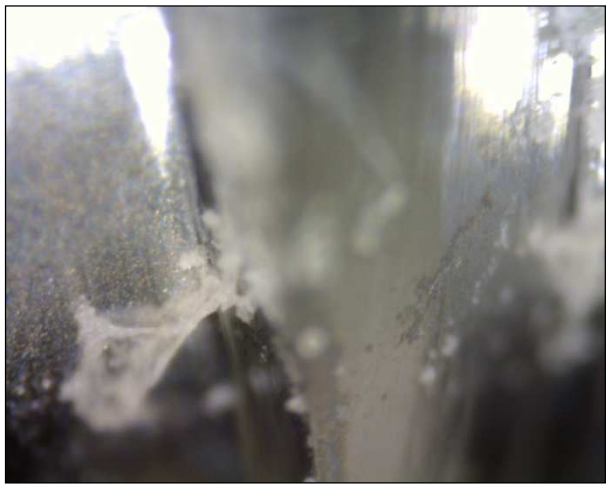


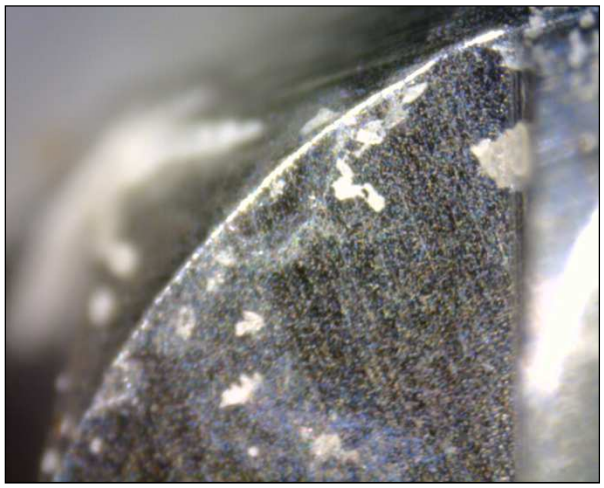


R10: Sample taken after standard use at the Neurosurgical Department (craniotomy)



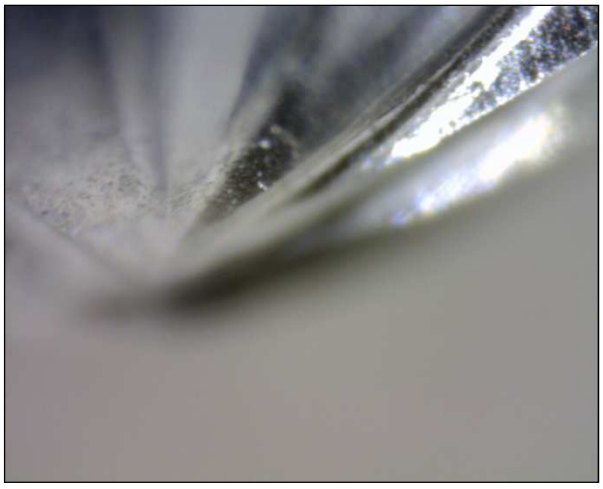
Before

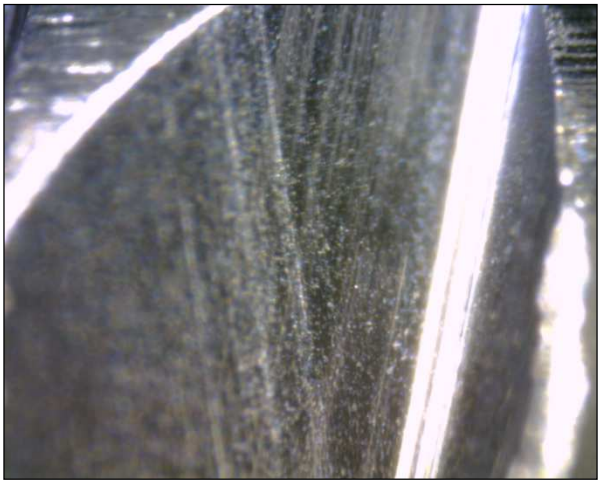




Cleaning:
40 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

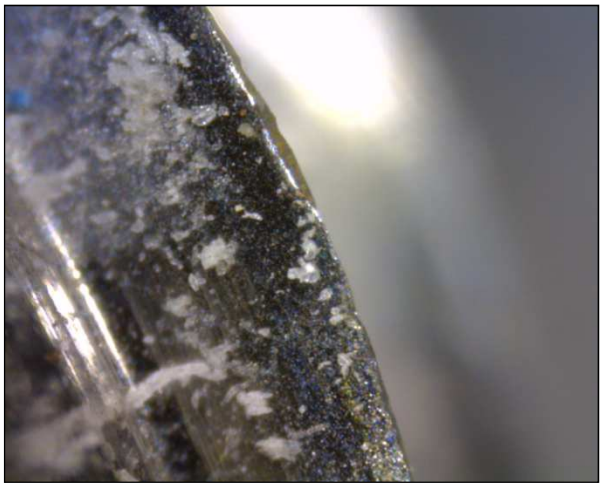
After





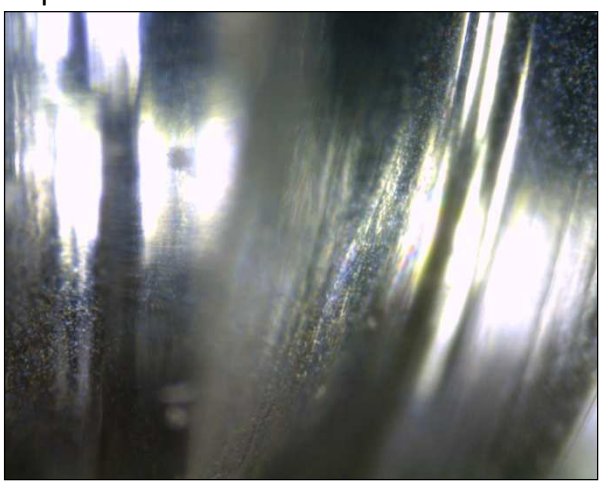
R12: Sample taken after standard use at the Neurosurgical Department (craniotomy)

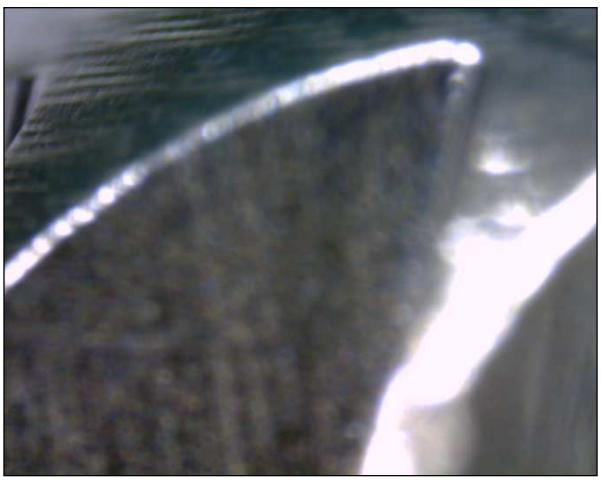
Before



Cleaning:
60 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

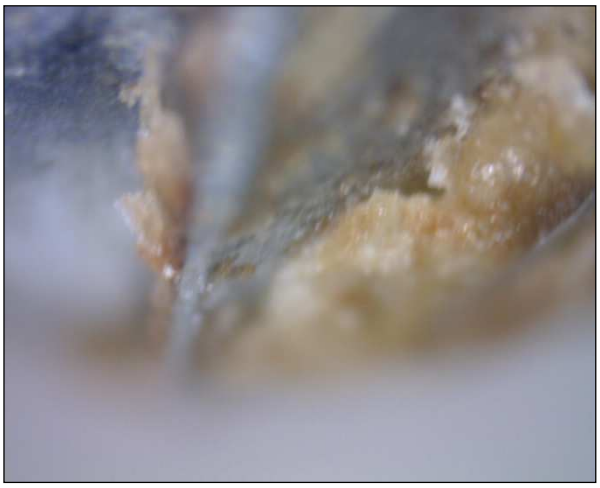
Dopo





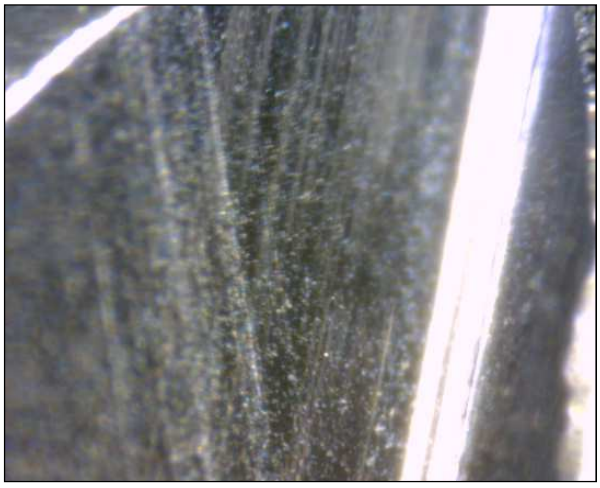
R13: Sample taken after standard use at the Neurosurgical Department (craniotomy)

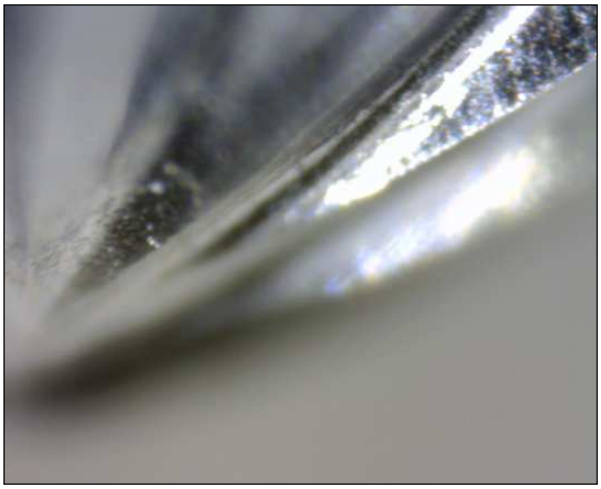
Before



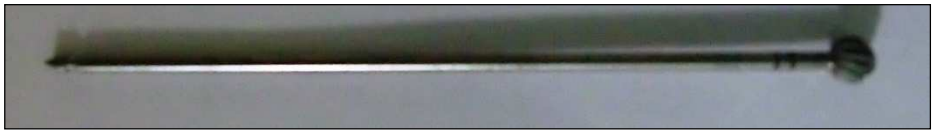
Cleaning:
60 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

After

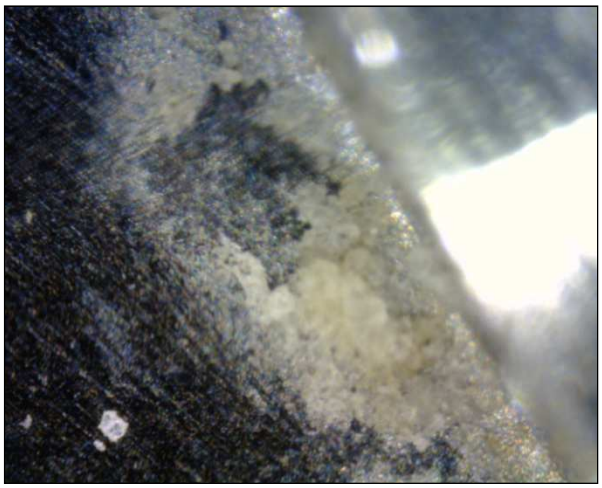


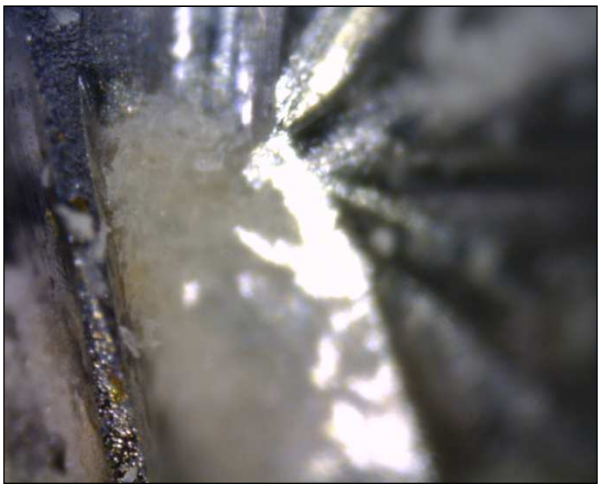


R14: Sample taken after standard use at the Neurosurgical Department (craniotomy)



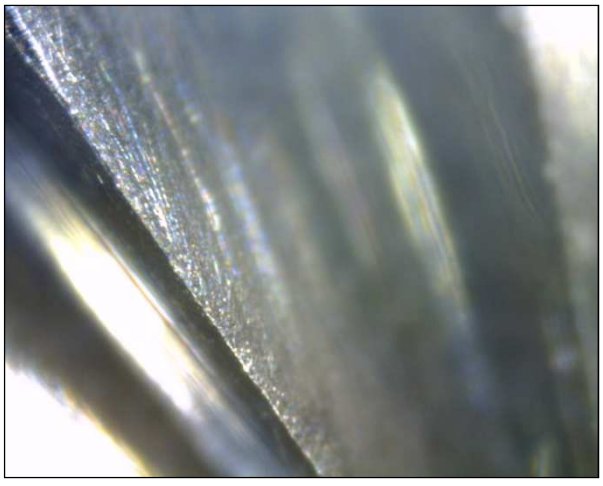
Before

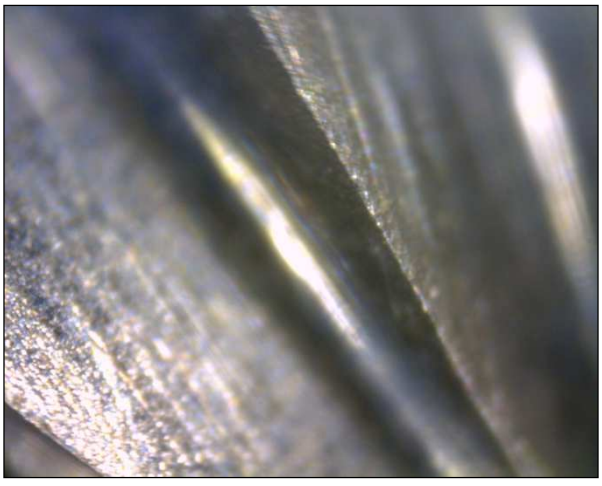




Cleaning:
60 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

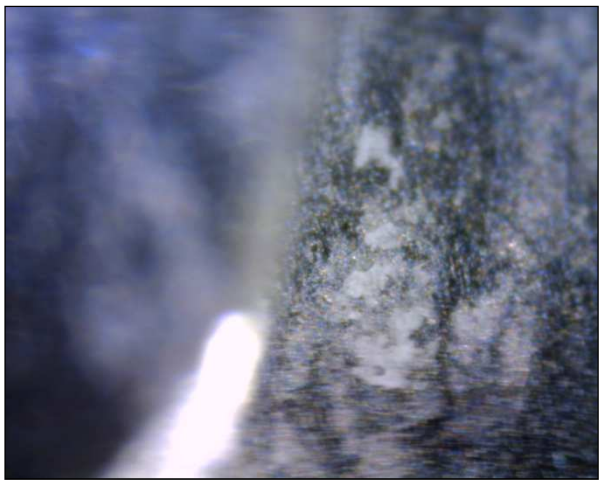
After





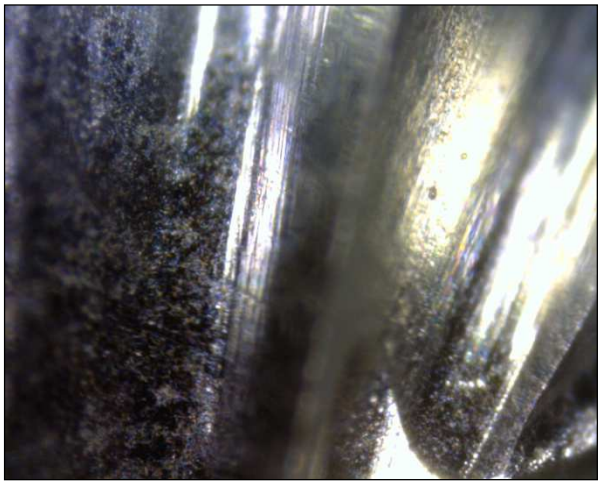
R15: Sample taken after standard use at the Neurosurgical Department (craniotomy)

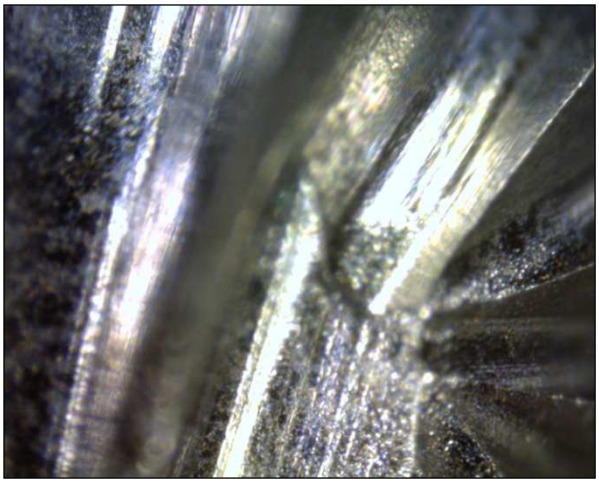
Before



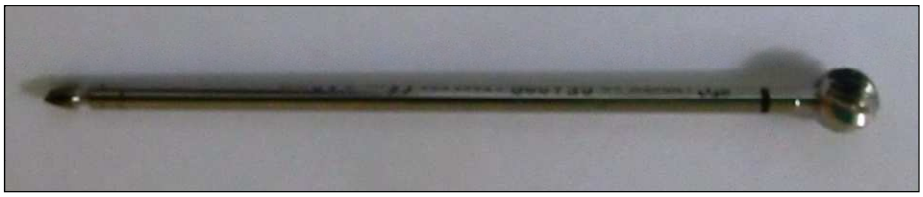
Cleaning:
60 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

After

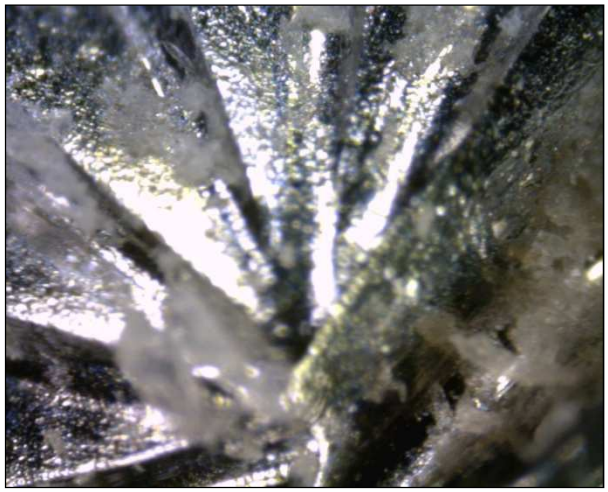




R16: Sample taken after standard use at the Neurosurgical Department (craniotomy)

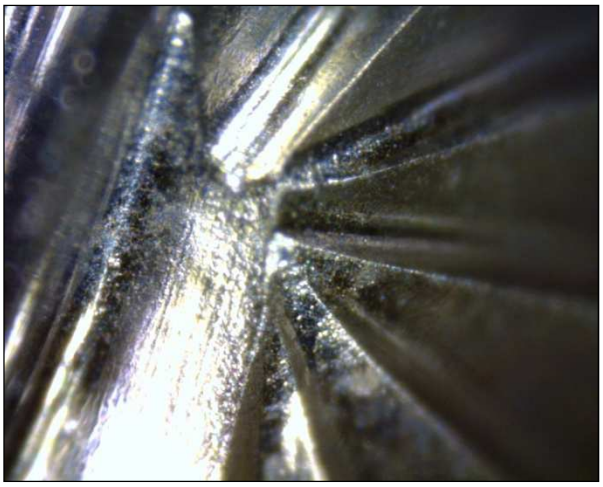


Before



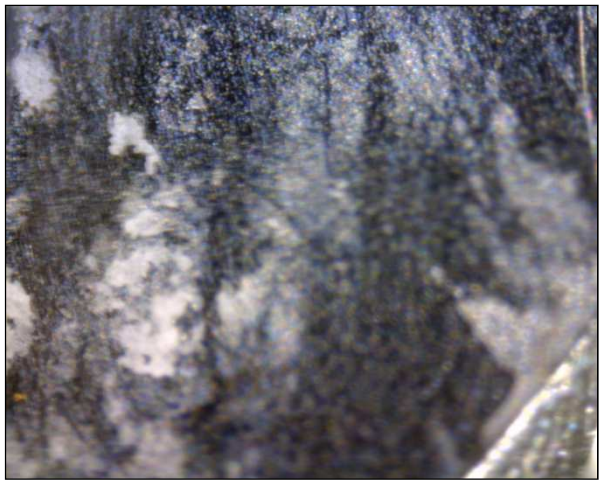
Cleaning:
60 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

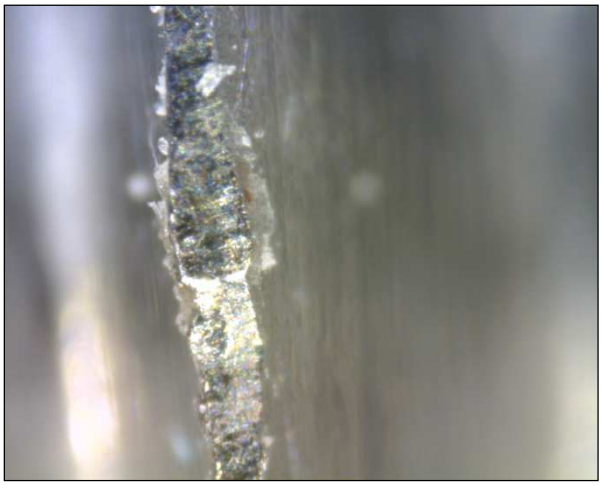
After



R17: Sample taken after standard use at the Neurosurgical Department (craniotomy)

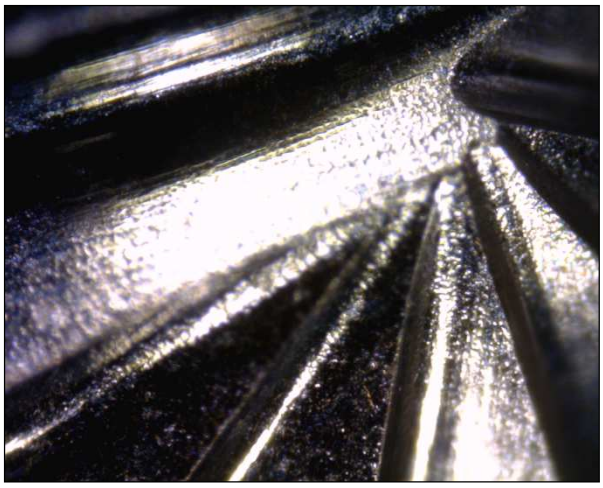
Before





Cleaning:
60 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

After



RP26: Standard monitoring cycle of model under study taken from the Neurosurgical Department after normal clinical practice (craniotomy)

Cleaning:
Standard decontamination process which entails:

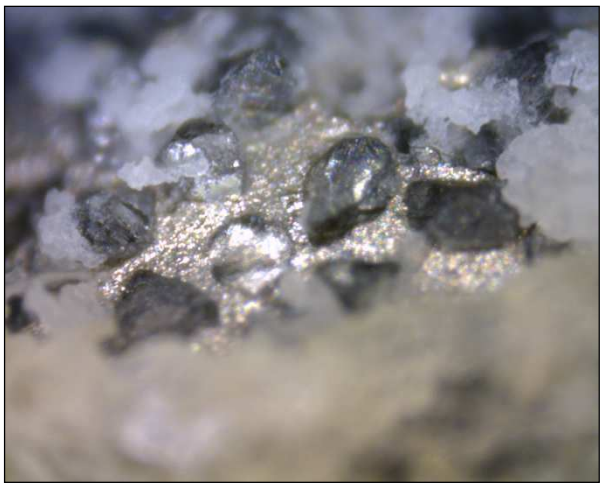
1. Cleaning: Manual brushing of the said instrument
2. Soaking in enzymatic liquid
3. Immersion in an ultrasonic machine (0.5% dilution, for 5 minutes at a temperature of 30 °C)
4. Rinsing

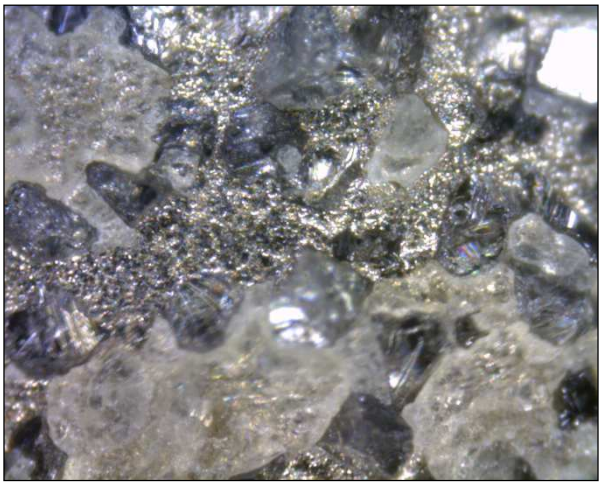
Diamond Burr GE517R

DS3: Stressed Sample

- Used on anatomical tissue (Skull Bone) in autopsy room
- 2:05 minutes of continuous milling on a 5 x 3 cm surface

Before



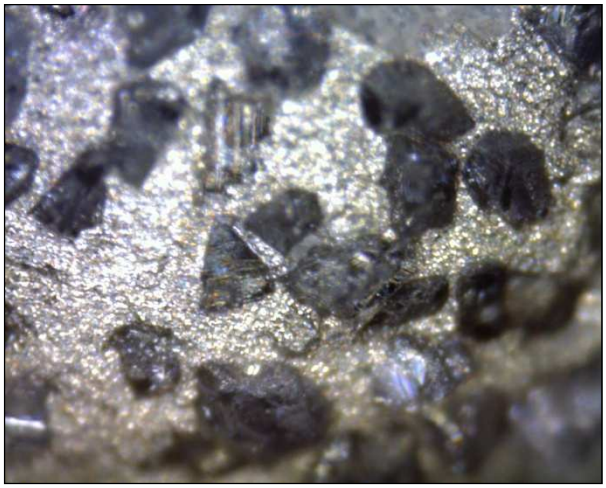


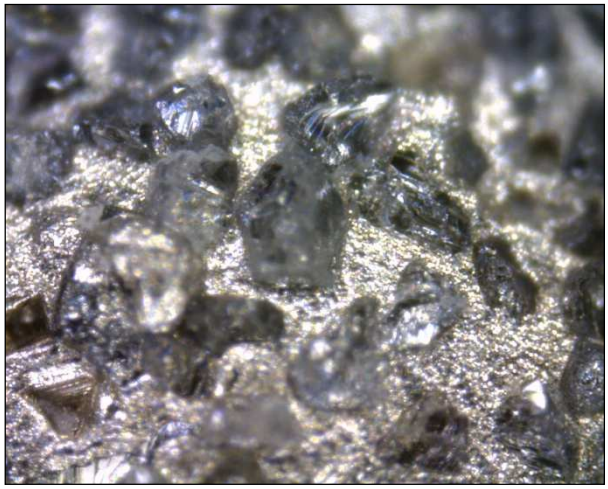
Cleaning:
30 seconds exposure to MELTRON® GG
Pressure 3 bar - Distance 5 - 10 cm – Rinsing and Blowing

Machine Inspection:
During the first few tests a malfunction occurred inside the cabin resulting in an inefficient cleaning process; the test was repeated after troubleshooting.

Cleaning:
40 seconds exposure to MELTRON® GG
Pressure 3 bar - Distance 5 - 10 cm – Rinsing and Blowing

After

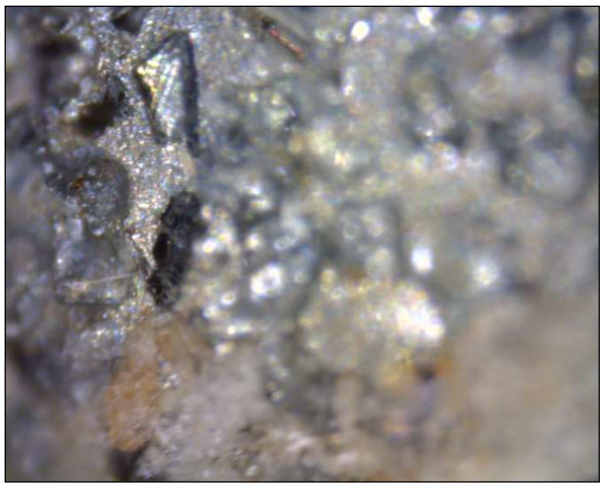




DS6: Stressed Sample

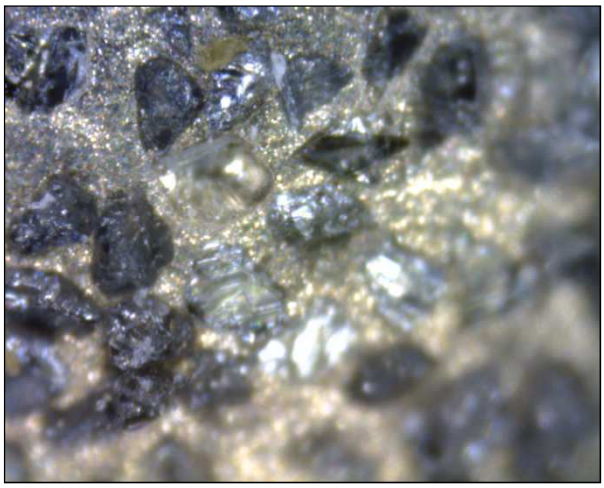
- Used on anatomical tissue (Skull Bone) in autopsy room
- 2:40 minutes of continuous milling on a 5 x 10 cm surface

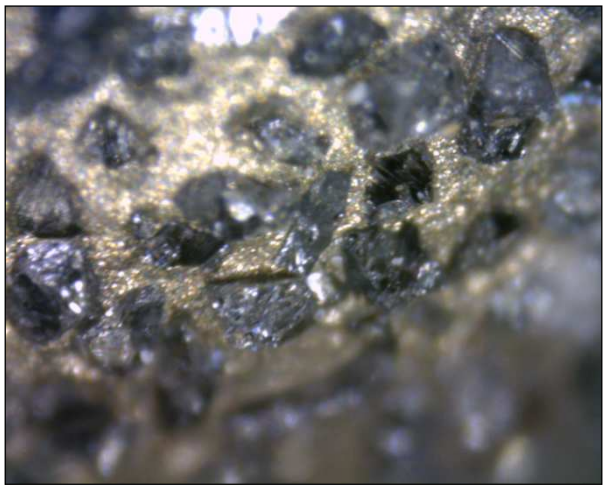
Before



Cleaning:
80 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

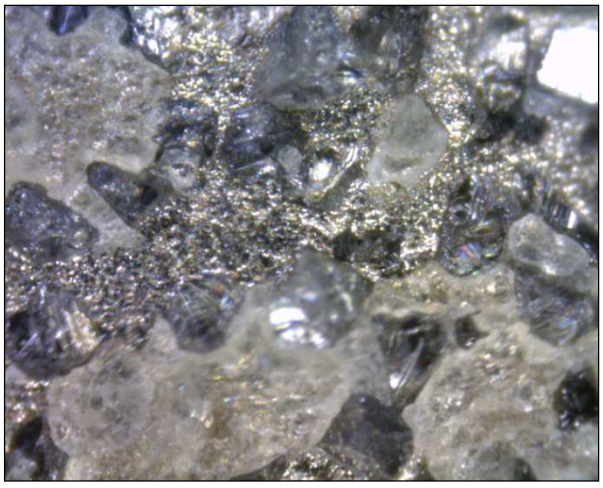
After

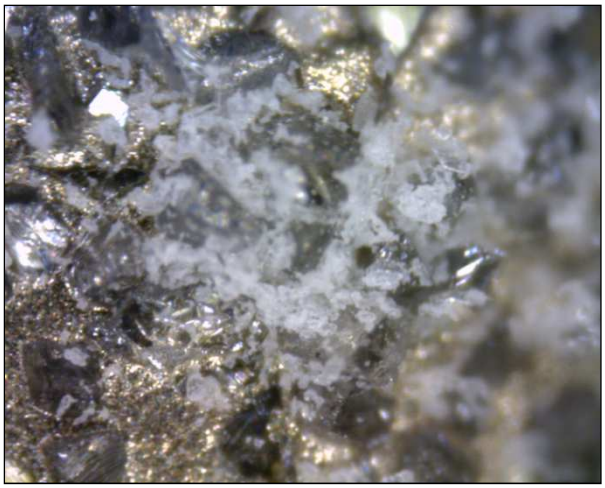




D8: Sample taken after standard use at the Neurosurgical Department (craniotomy)

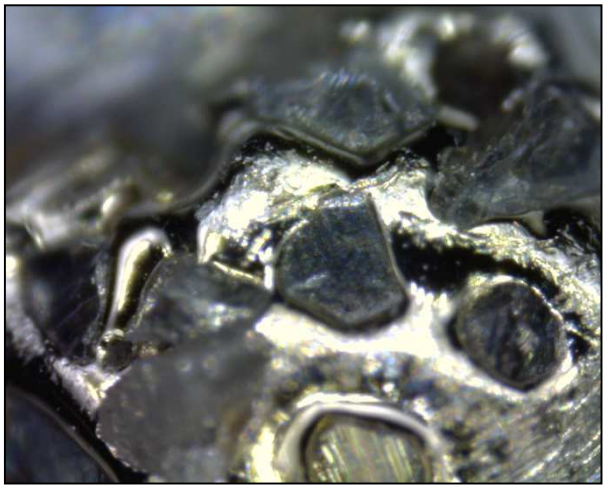
Before



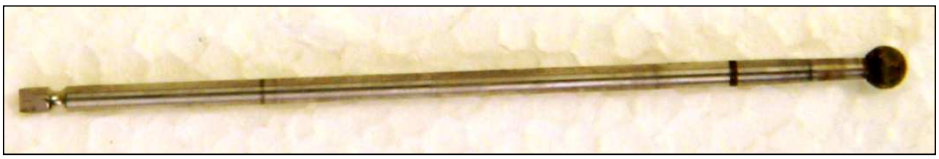


Cleaning:
30 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

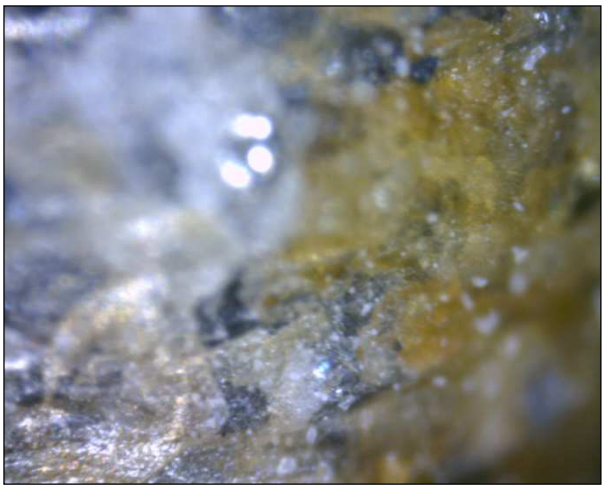
After



D9: Sample taken after standard use at the Neurosurgical Department (craniotomy)

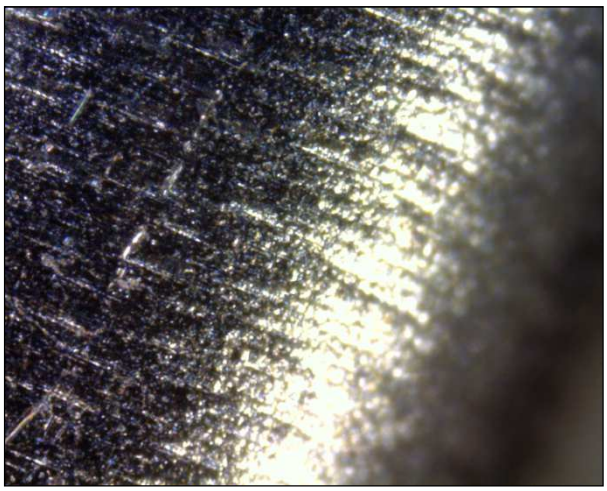


Before



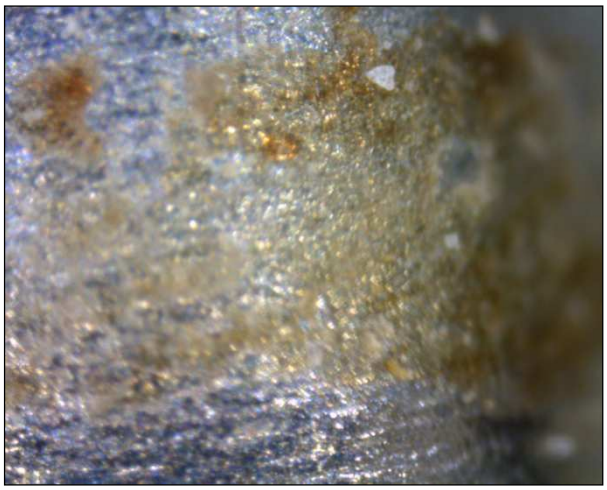
Cleaning:
30 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

After



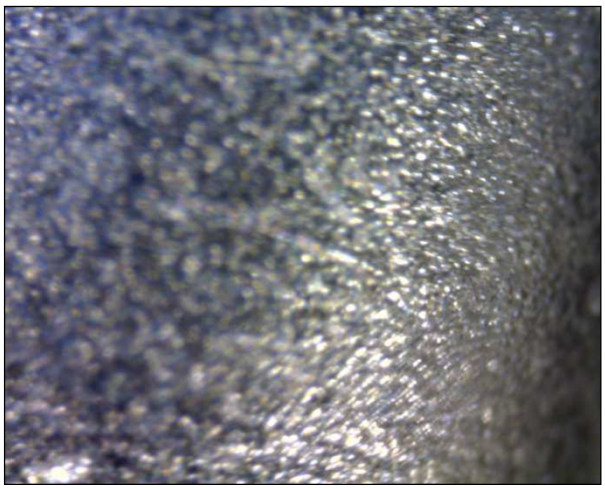
D22: Sample taken after standard use at the Neurosurgical Department (craniotomy)

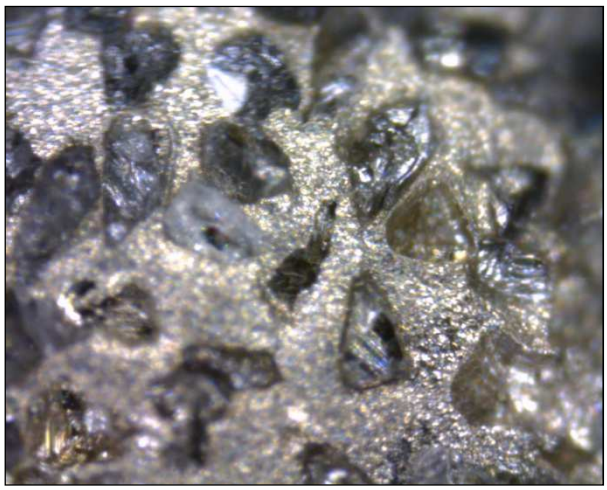
Before



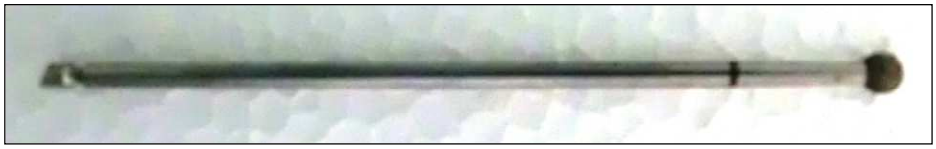
Cleaning:
43 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

After





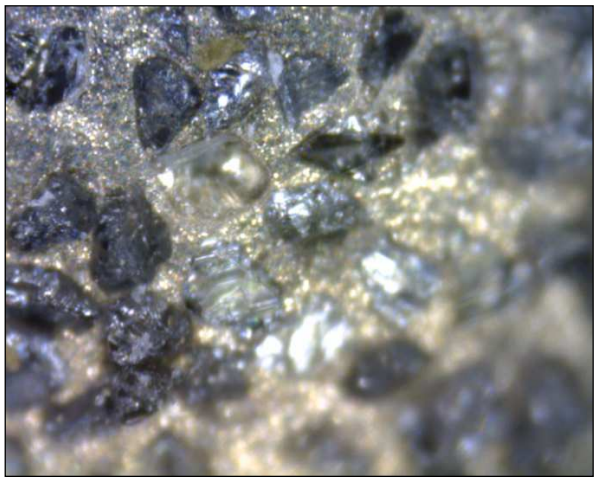
D24: Sample taken after standard use at the Neurosurgical Department (craniotomy)



Before

Cleaning:
60 seconds exposure to MELTRON® GG
Pressure 3.5 bar - Distance 5 - 10 cm – Rinsing and Blowing

After

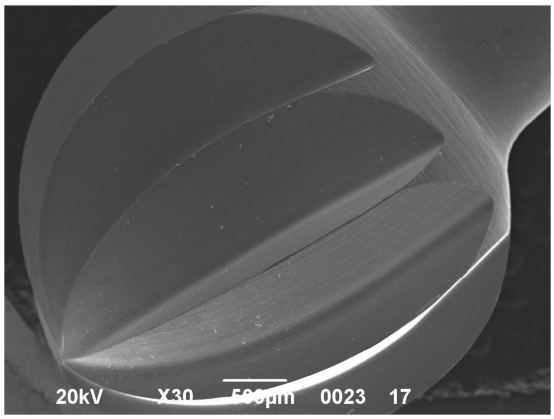


DP27: Standard monitoring cycle of model under study taken from the Neurosurgical Department after normal clinical practice (craniotomy)

Cleaning:
Standard decontamination process which entails:

1. Manual brushing of the said instrument
2. Soaking in enzymatic liquid
3. Immersion in an ultrasonic machine (0.5% dilution, for 5 minutes at a temperature of 30°C)
4. Rinsing

The three control samples, unused, Rosen Burr RN29 (n. 12-S-0017), Diamond Burr DN30 (n. 12-S-0019) and Craniotome Burr CN28 (n. 12-S-0018) had intact surfaces without any imperfections.



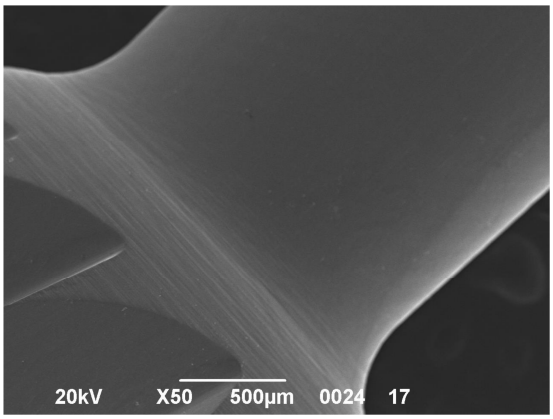
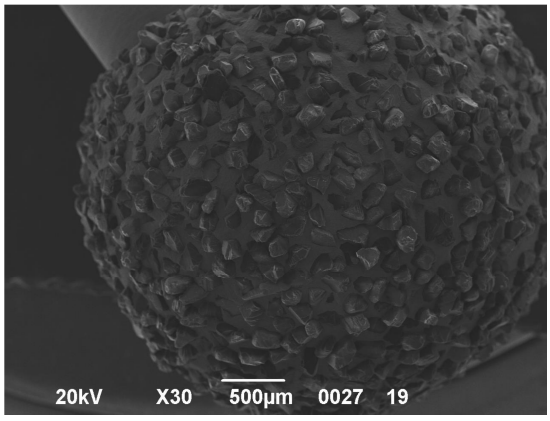


Fig.1 – Rosen Burr RN29



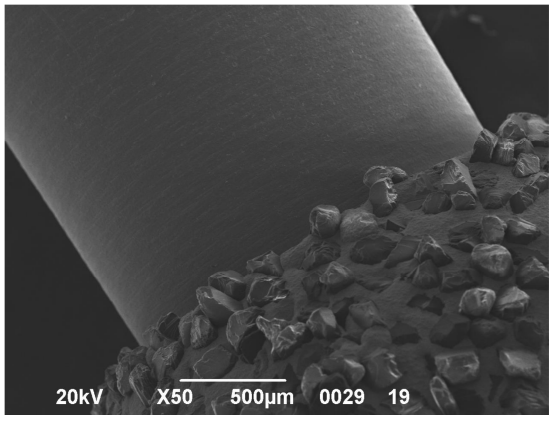
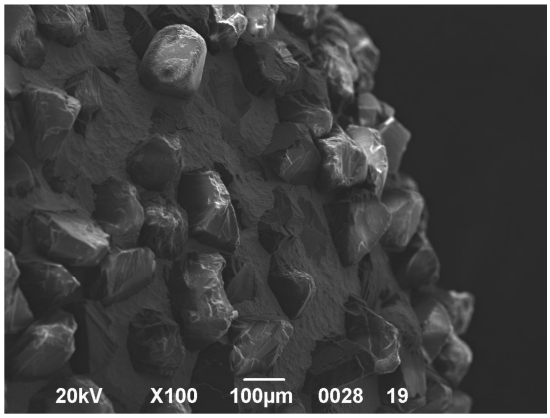


Fig. 2 – Diamond Burr DN30



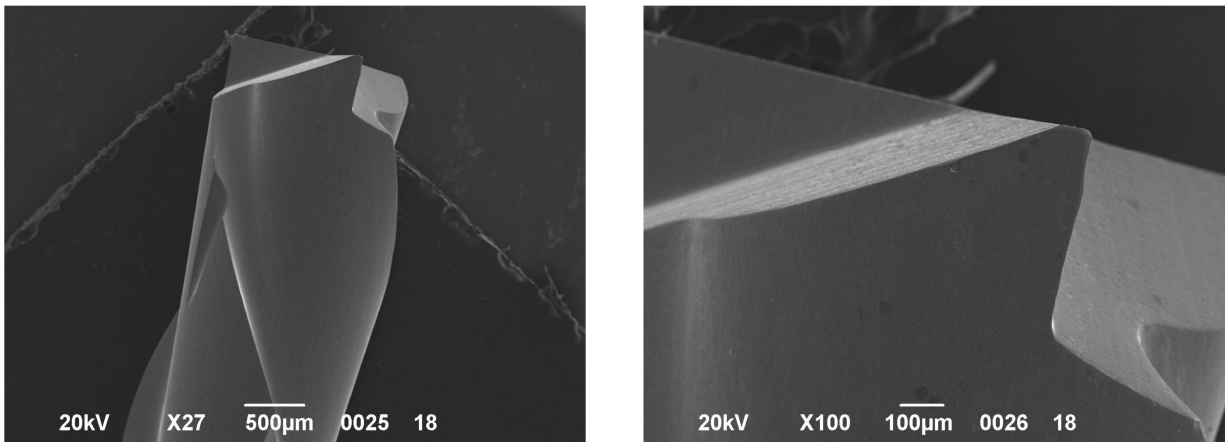
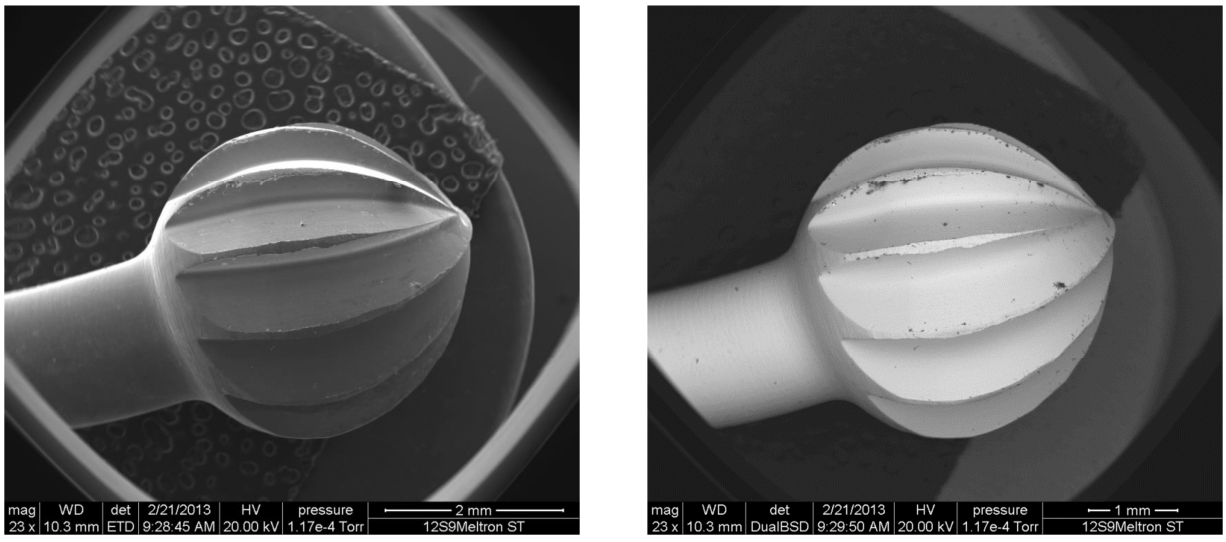
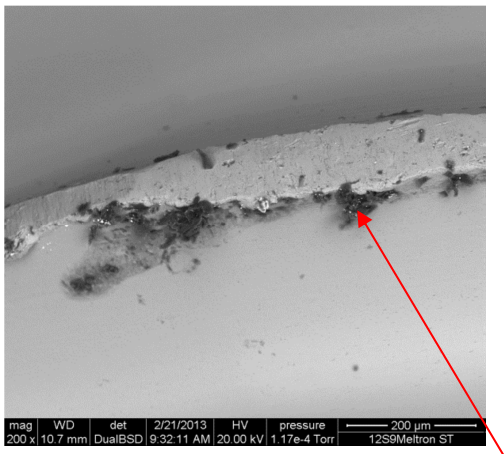


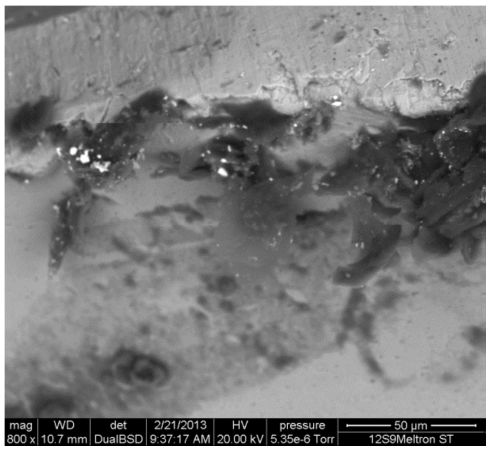
Fig. 3 - Craniotome CN28

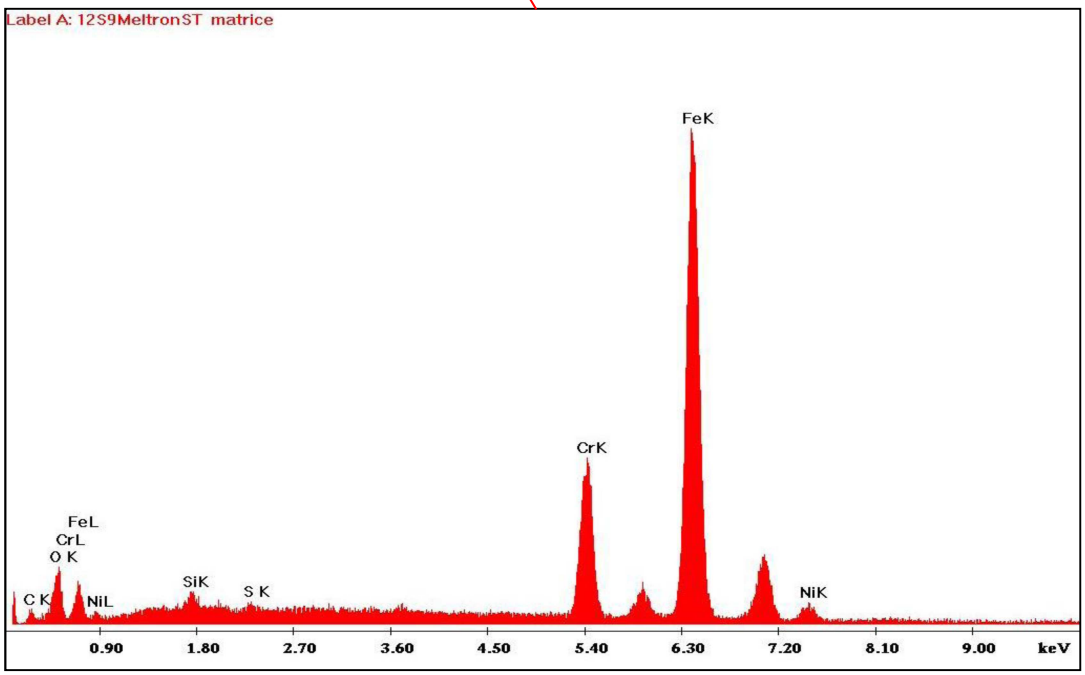
As regards the treated samples, the results are as follows:

BICARJET® treated Rosen Burr R13 (n. 12-S-0009): the burr's stainless steel surface is slightly altered especially along its protrusion where small-scale particles were detected, whose area amounted to 1.14% of the total burr area. These particles have a varied chemical composition: gold, carbon, chlorine, potassium, sodium and traces of other elements;

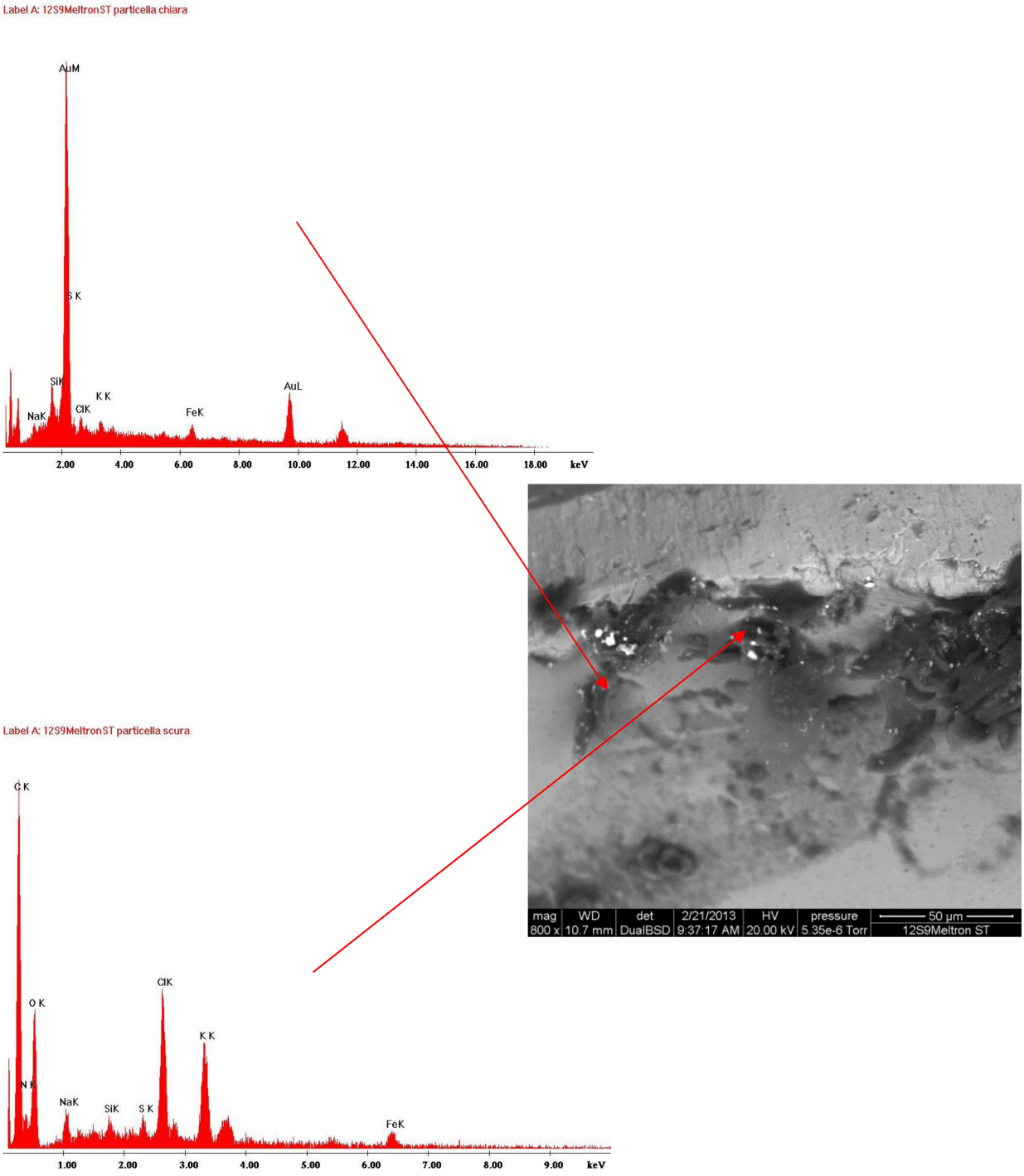






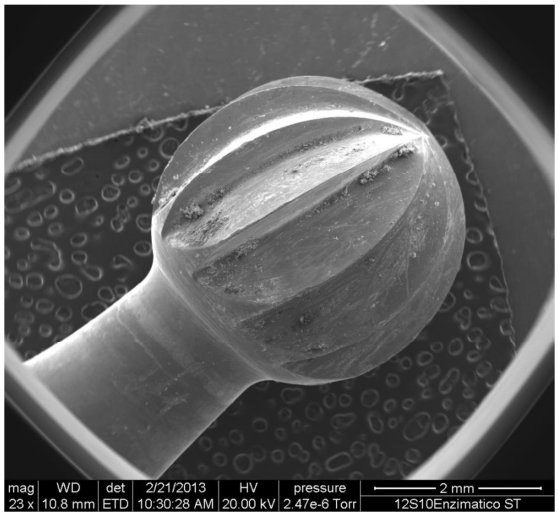


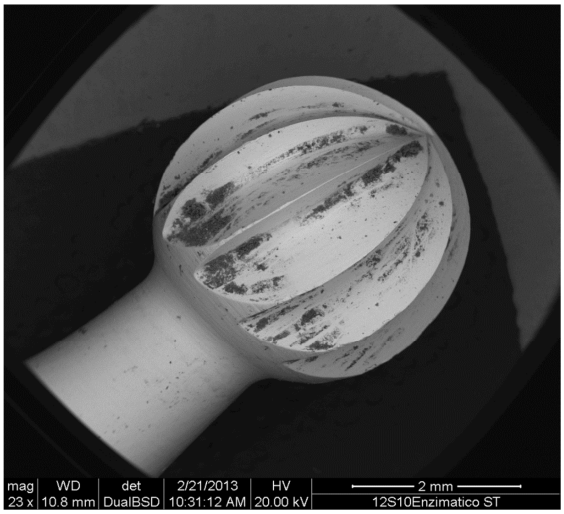
MICROANALYSIS OF THE MATRIX: The main elements detected are IRON, NICKEL, CHROME identifiable as steel

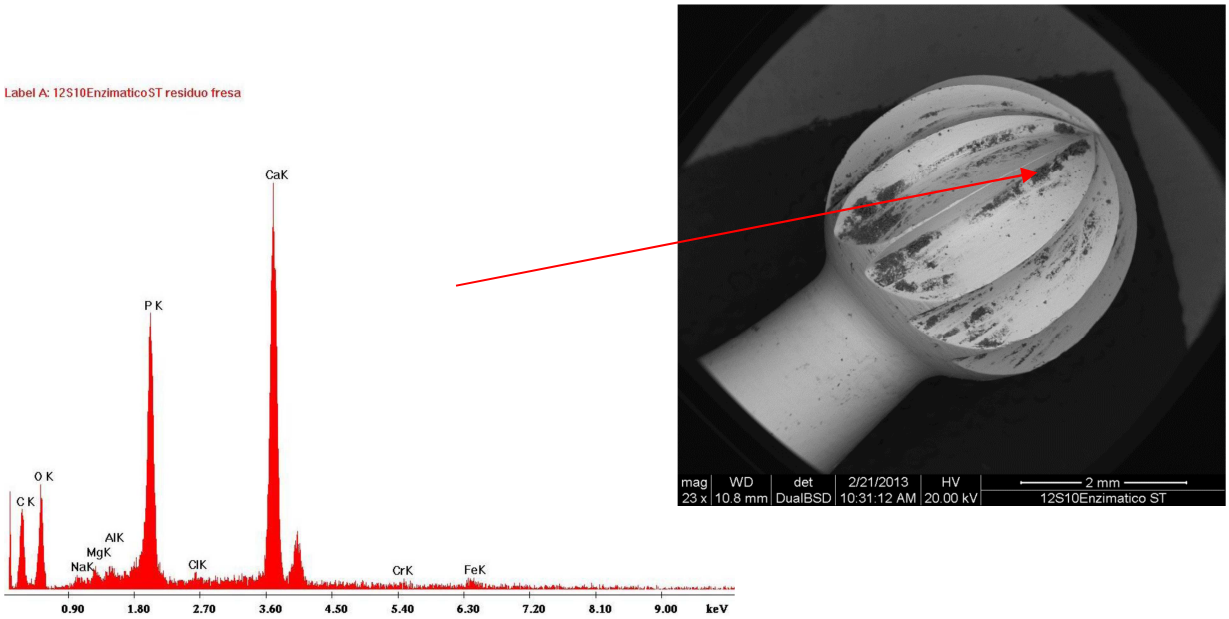


MICROANALYSIS OF PARTICLES: The main elements detected are GOLD AND IRON in the clear particle (pollutants of prepared samples, above), CARBON, CHLORINE, POTASSIUM and SODIUM in the dark particle (organic compound and saline residue)

Standard treated Rosen Burr RP26 (n. 12-S-0010): the burr's surface was notably altered; the dimensions of the particles detected were rather extensive. The total area covered was of 9.28%. These particles have a uniform chemical composition: calcium, phosphorus, oxygen (connective tissue residue) and traces of other elements were mainly found along the burr's protrusions and cavities.

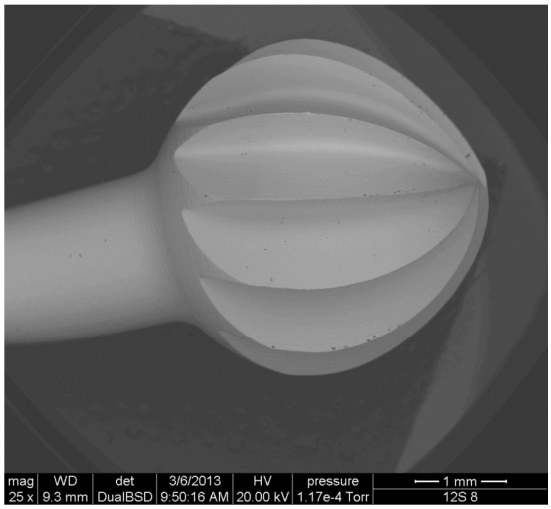


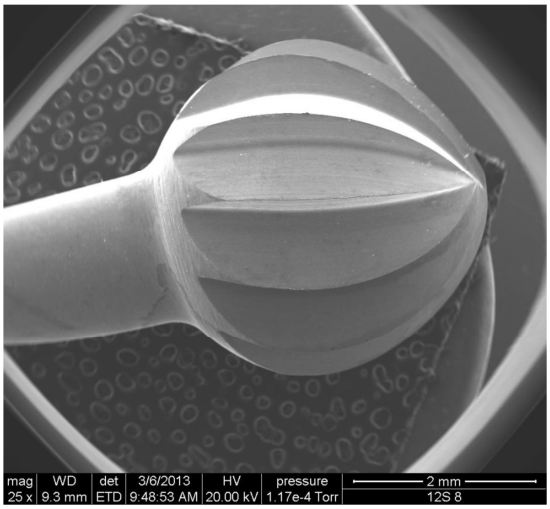


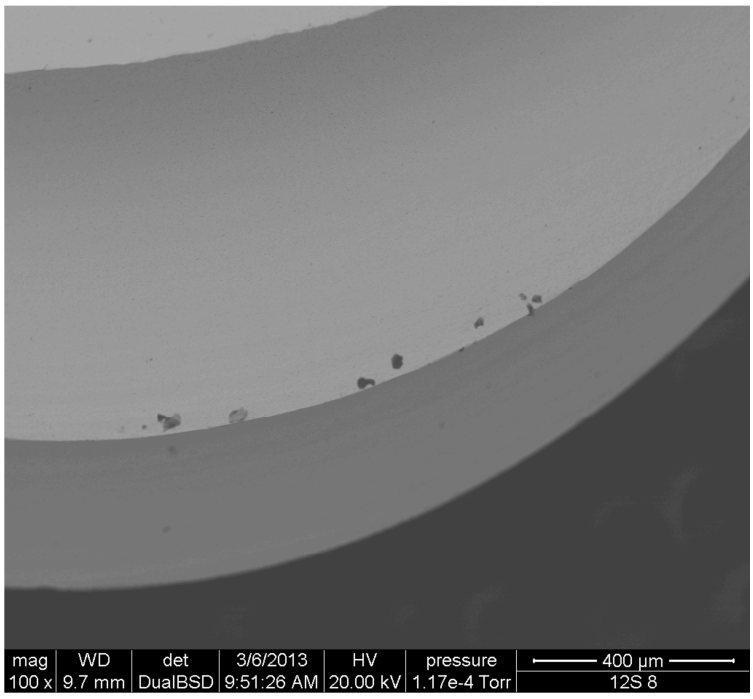


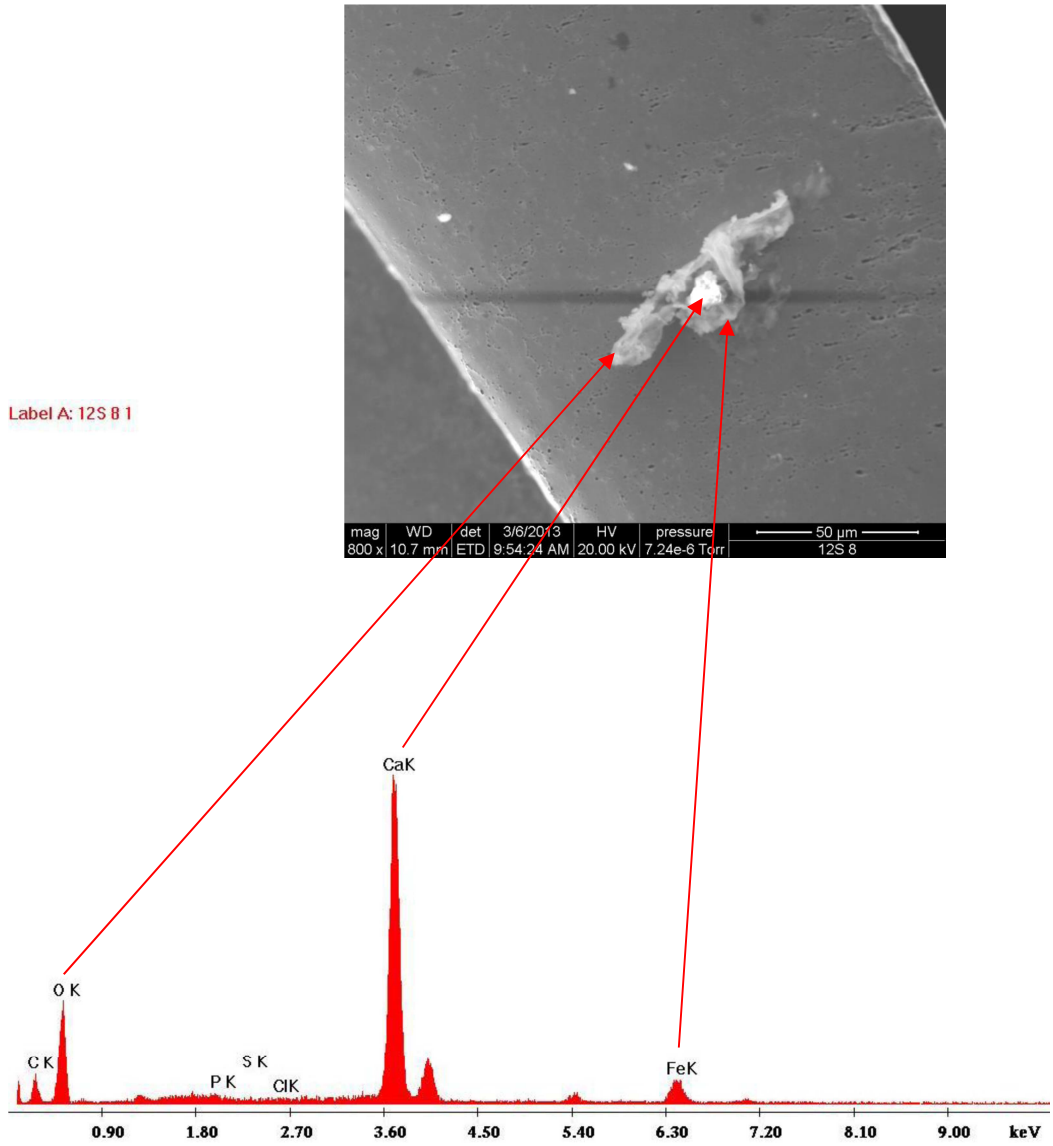
MICROANALYSIS OF THE DARK PARTICLE: The main elements detected are CALCIUM, PHOSPHORUS, OXYGEN (connective tissue residue)

BICARJET® treated "stressed" Rosen Burr RS5 (n. 12-S-0008): the burr's surface is slightly altered especially along its protrusion where small-scale particles were detected, whose area amounted to 0.21% of the total burr area. These particles have a varied chemical composition: calcium, oxygen, iron, potassium, and traces of other elements;



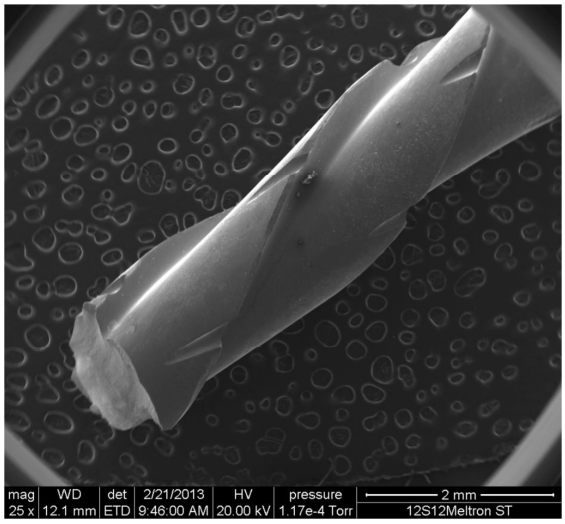


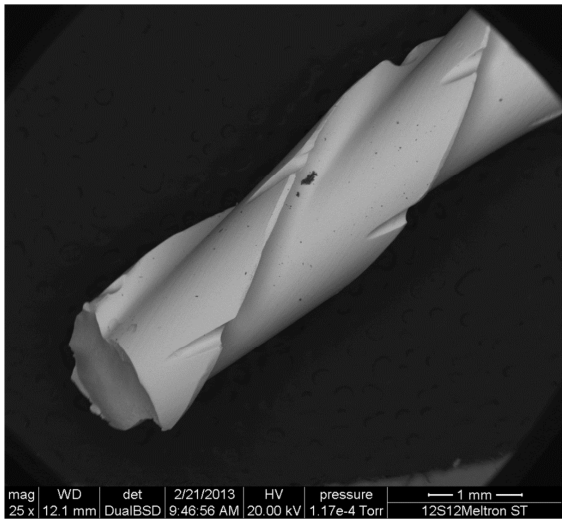


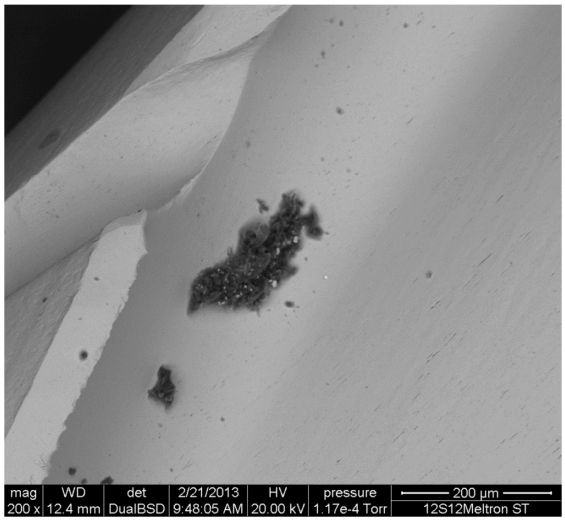


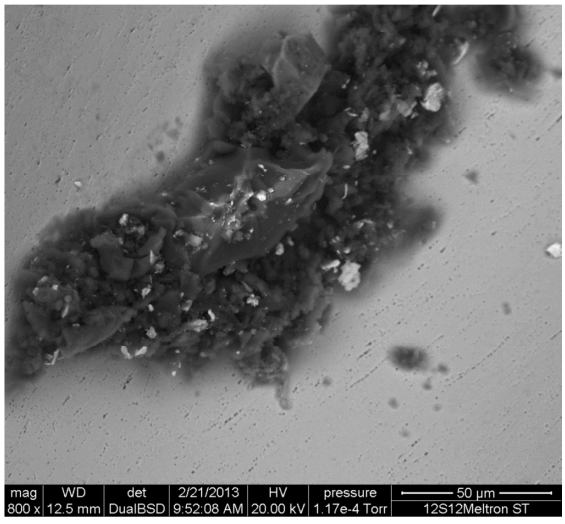
MICROANALYSIS OF THE PARTICLE: The main elements detected are CALCIUM, OXYGEN and IRON representative of the saline compound containing calcium but no connective tissue residue.

BICARJET® treated Craniotome C20 (n. 12-S-0012): the craniotome's surface resulted slightly altered as small-scale particles were detected. The area amounted to 0.25% of the total craniotome. The particles have a varied chemical composition: chlorine, carbon, oxygen and copper, zinc (brass), iron and traces of other elements;

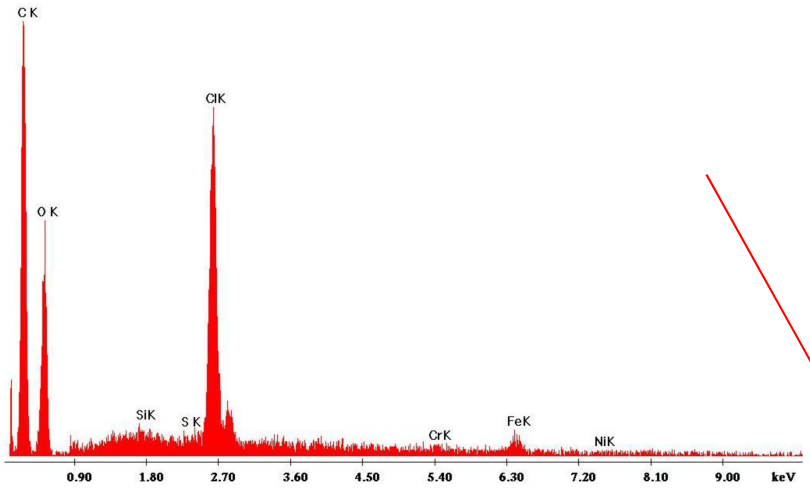


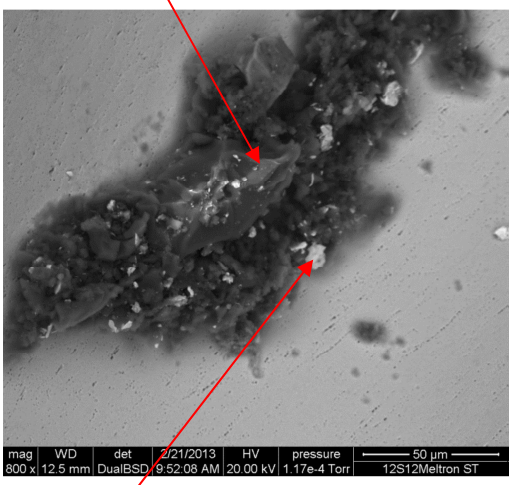






Label A: 12S12MeltronST scuro





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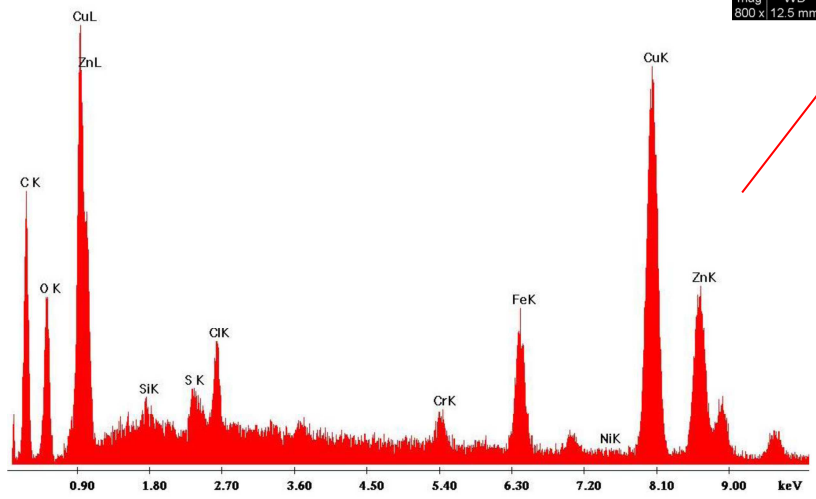
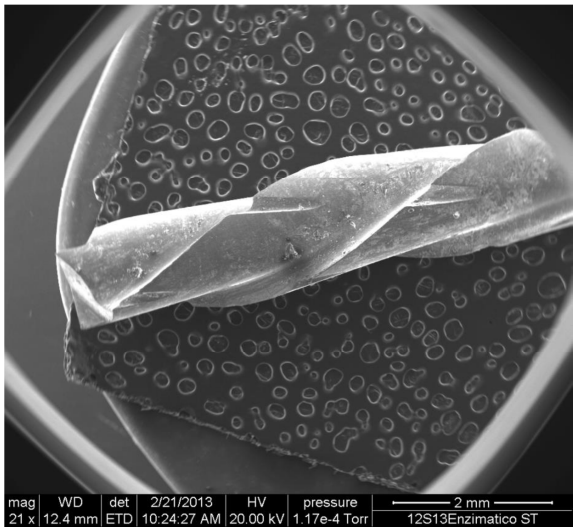
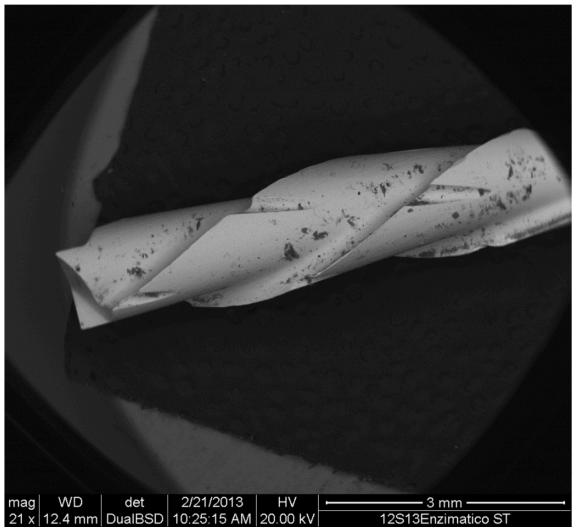


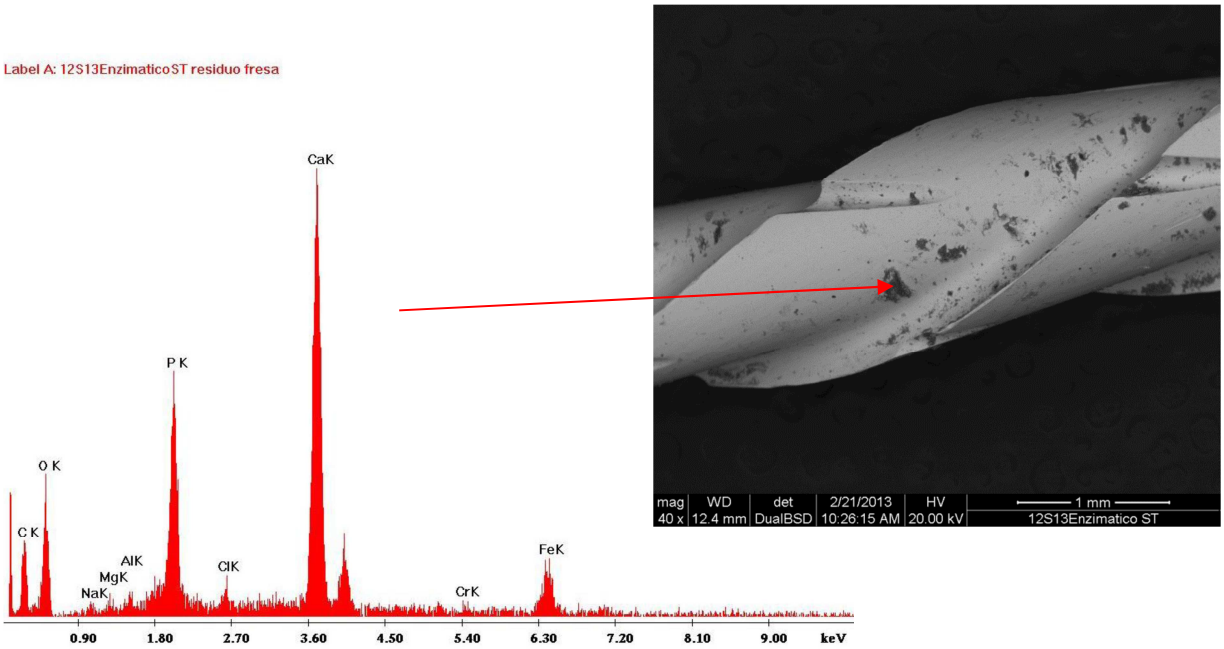
MICROANALYSIS OF THE DARK PARTICLE (higher spectrum): The main elements detected are CHLORINE, CARBON, OXYGEN comprising the saline compound.

MICROANALYSIS OF THE LIGHT PARTICLE (lower spectrum): The main elements detected are COPPER, ZINC, and IRON constituting a metallic layer (brass) deriving from the distribution system of saline compound.

Standard treated Craniotome CP25 (n. 12-S-0013): the craniotome's surface was notably altered; the dimensions of the particles detected were of medium size. The area covered was of 4.19% of the total craniotomies. These particles have a uniform chemical composition: calcium, phosphorus, oxygen (connective tissue residue) and traces of other elements;

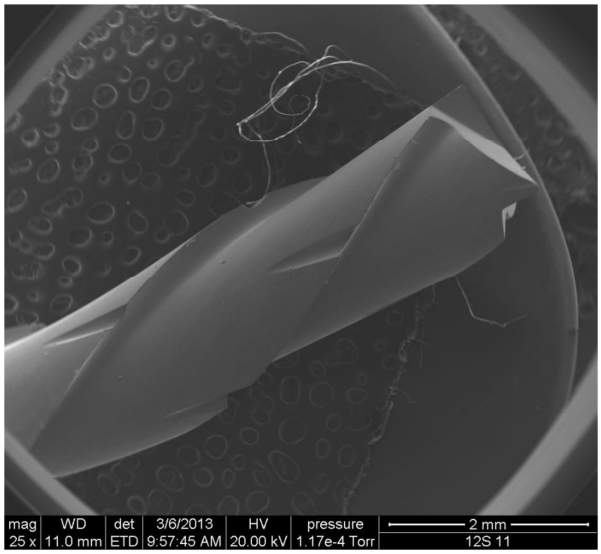


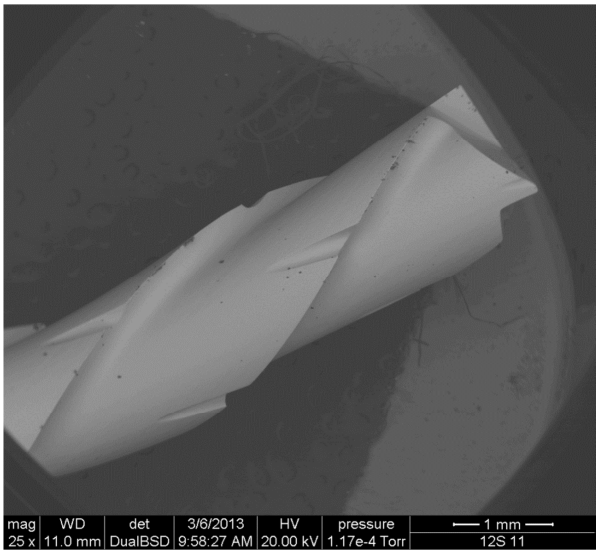


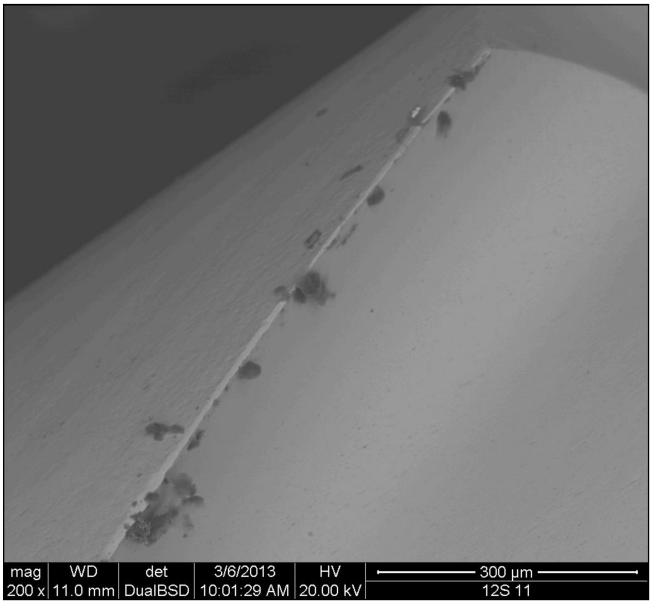


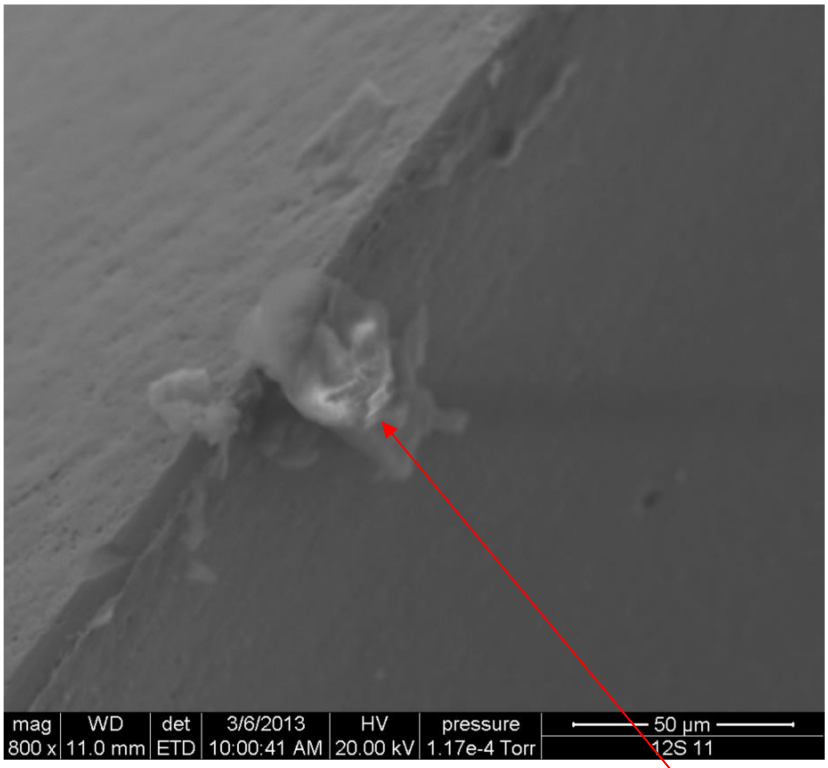
MICROANALYSIS OF SMALL DARK PARTICLES: The main elements detected are CALCIUM, PHOSPORUS, and OXYGEN (connective tissue residue).

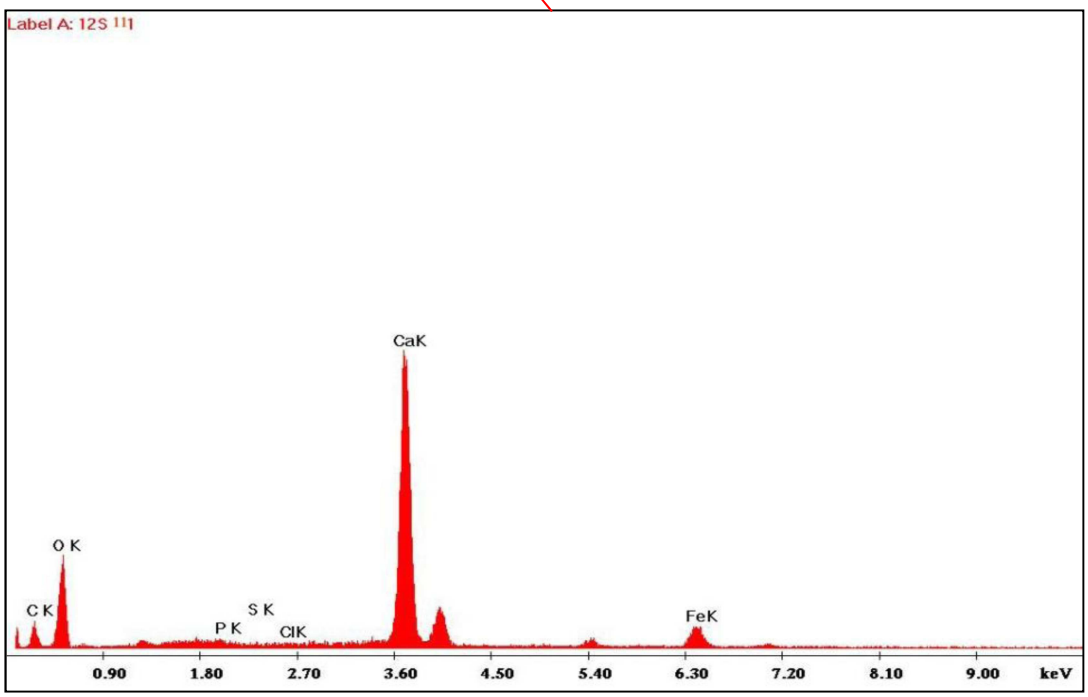
BICARJET® treated "stressed" Craniotome CS4 (n. 12-S-0011): the craniotome's surface resulted slightly altered; moreover small-scale particles were detected whose area amounted to 0.24% of the total craniotome area. The particles have a varied chemical composition: calcium, oxygen, iron and traces of other elements;





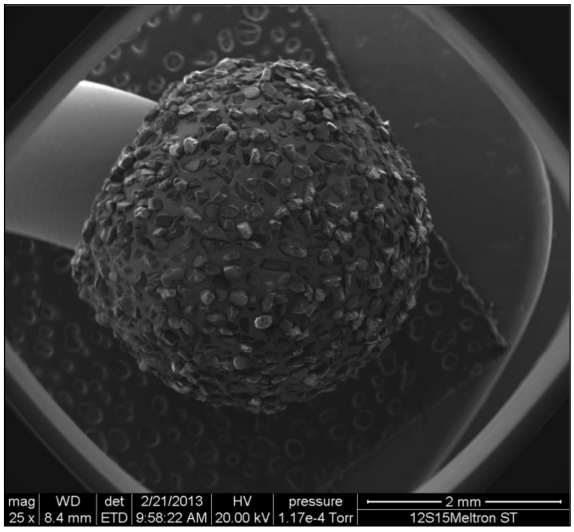


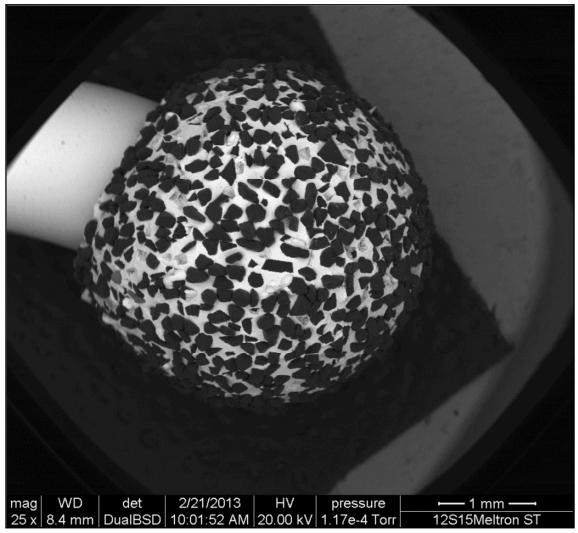


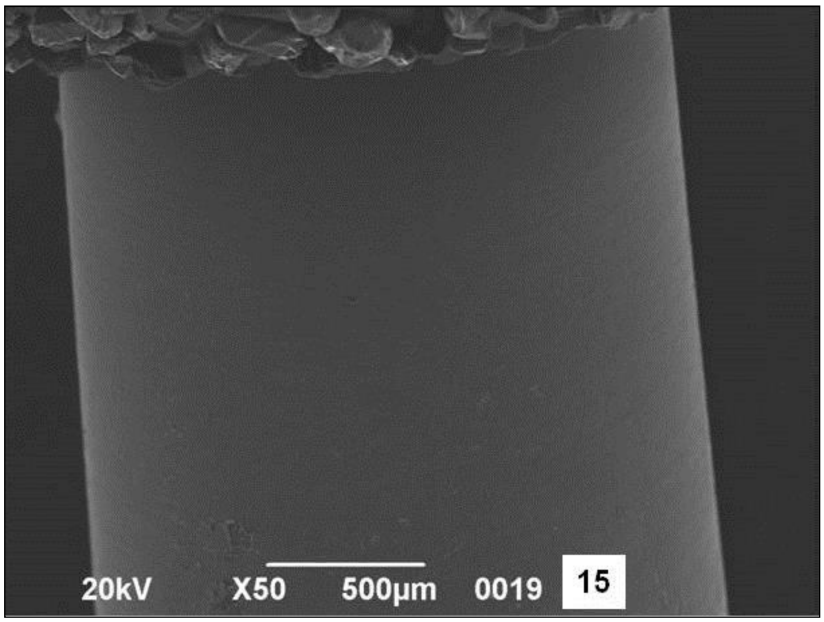


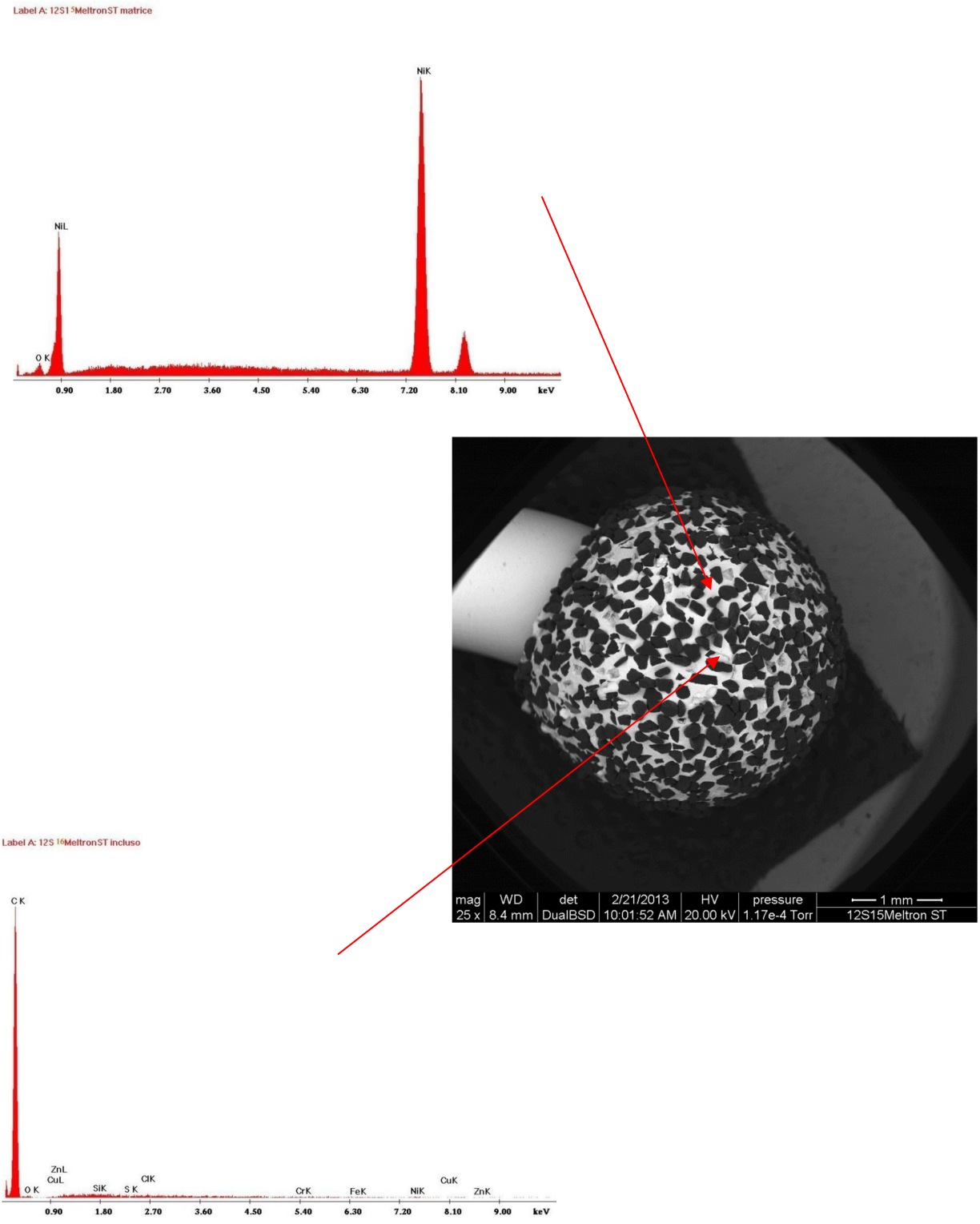
MICROANALYSIS OF SMALL PARTICLES: The main elements detected are CALCIUM, OXYGEN and IRON attributable to the saline compound containing calcium but not belonging to connective tissue residue.

BICARJET® treated Diamond Burr D24 (n. 12-S-0015): the head of the diamond burr, made of nickel and carbon (diamond), is intact; no external particles are noted on the surface.



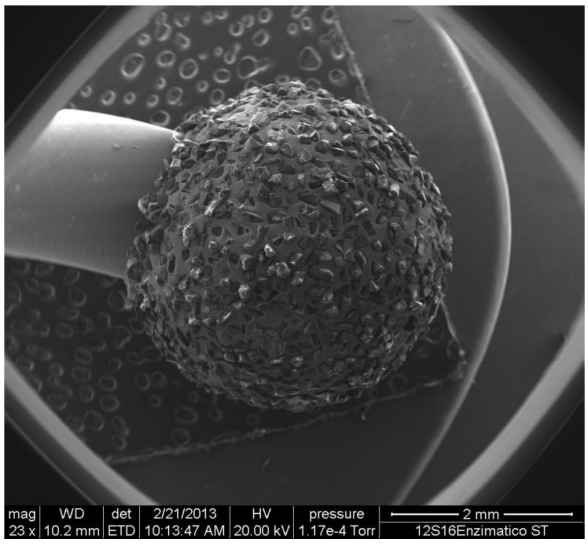


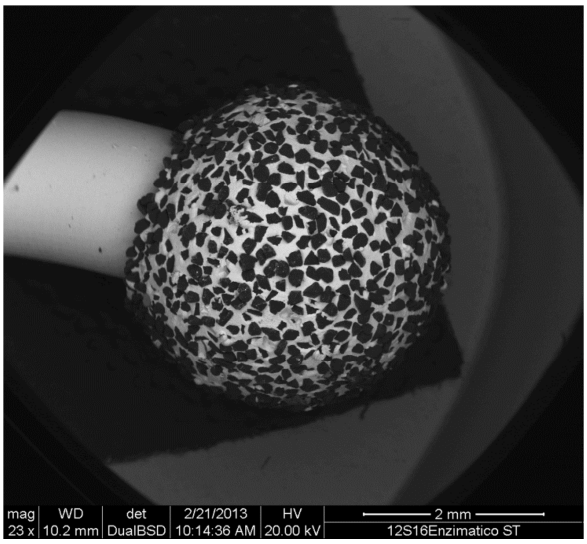


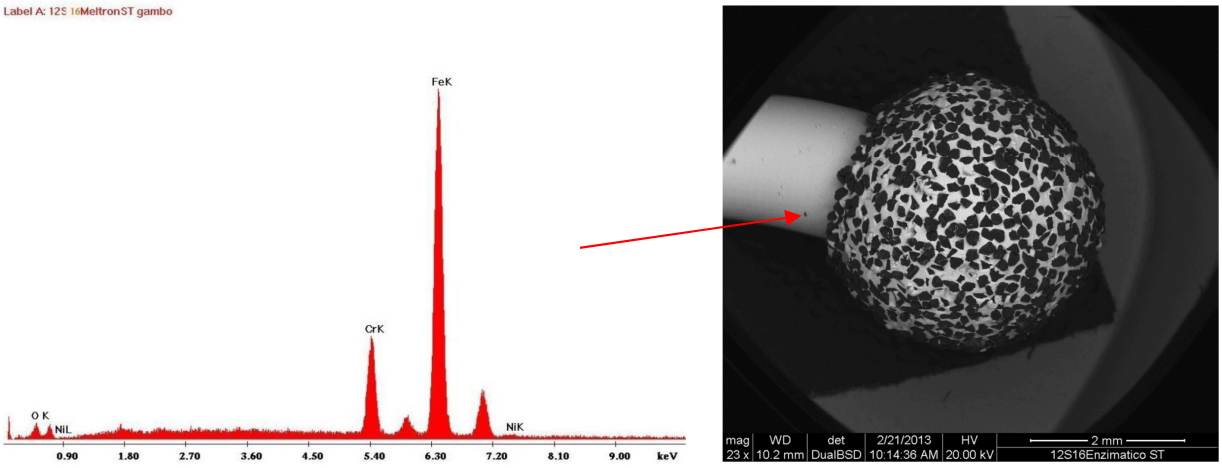


MICROANALYSIS OF PARTICLES: The main elements detected are NICKEL (higher spectrum) and CARBON (lower spectrum).

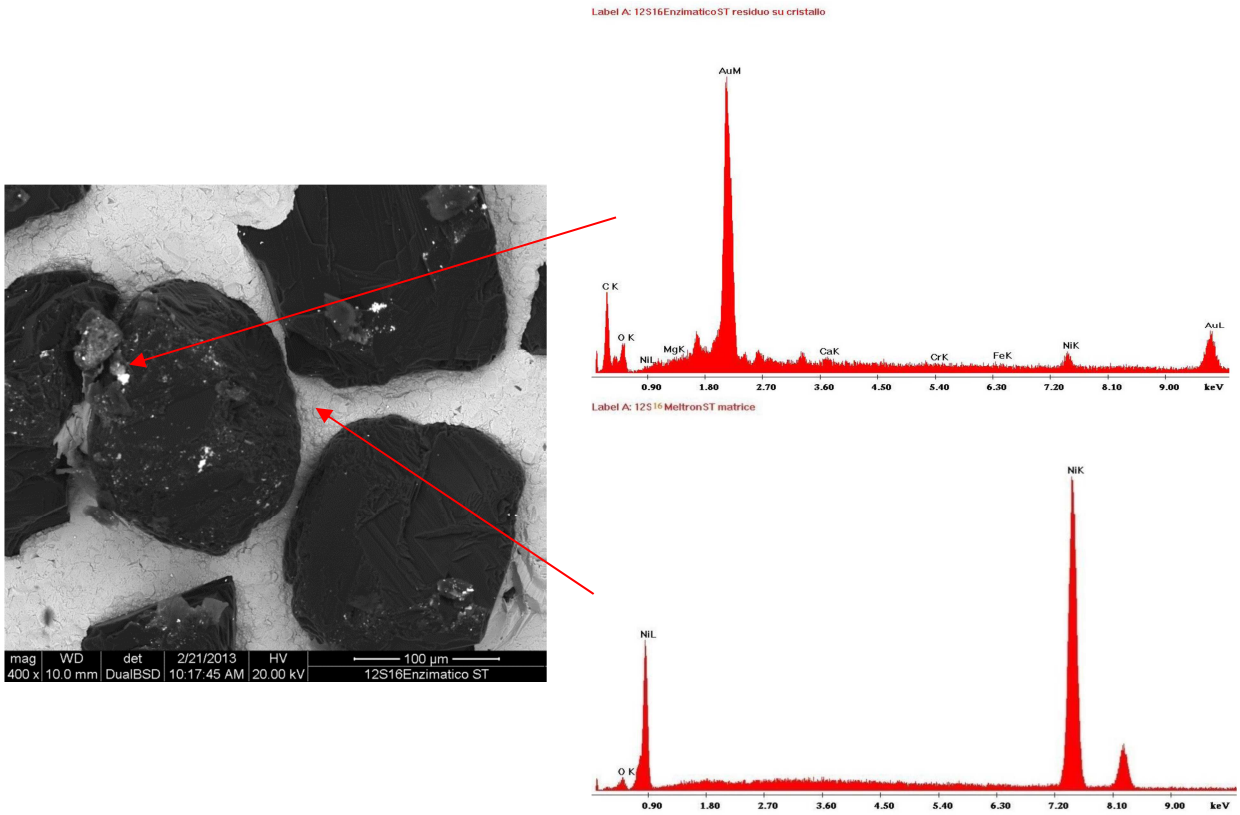
Standard treated Diamond Burr DP27 (n. 12-S-0016): the surface of the diamond burr does not appear to be altered except for some depression on the matrix due to diamond fragments absence. The small-scale particles detected were 0.23% of the total diamond area. These particles have a varied chemical composition: gold, nickel, iron (steel), oxygen, and traces of other elements;





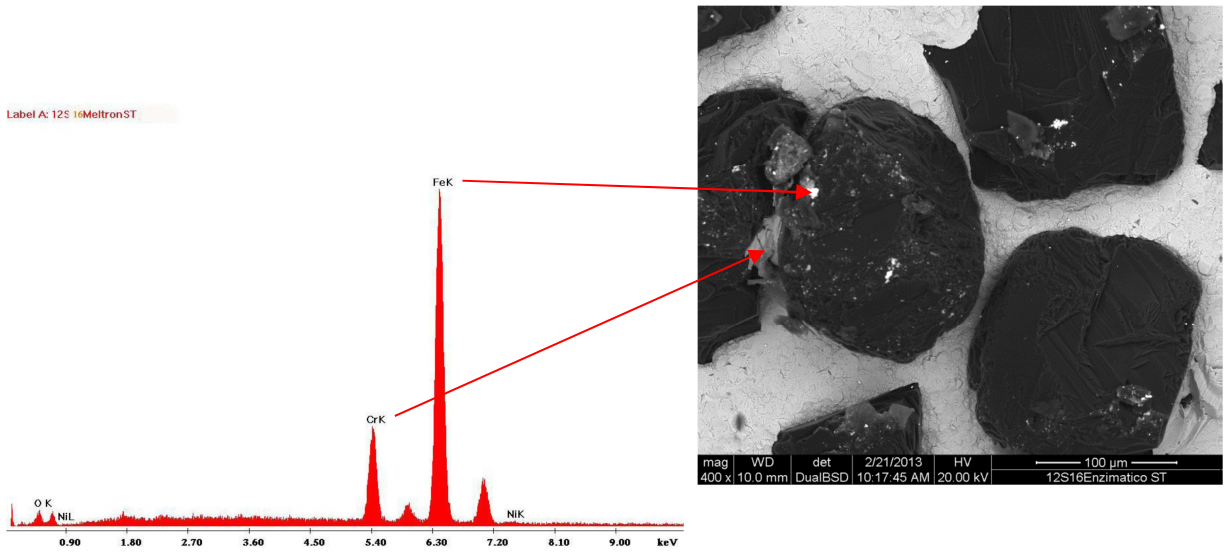


MICROANALYSIS OF PARTICLES ON STEM: The main elements detected are IRON, CHROME, and NICKEL (STEEL)



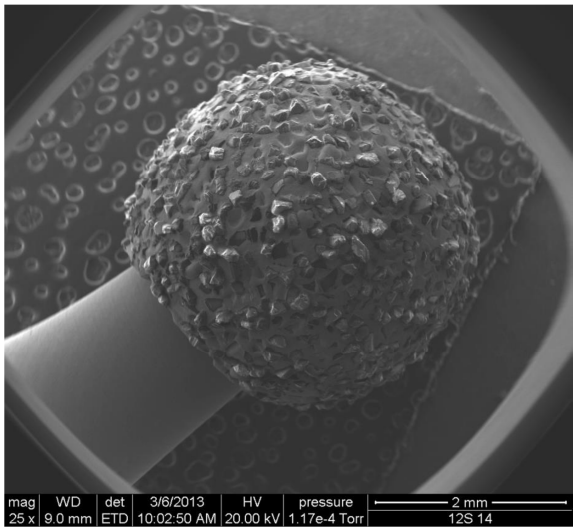
MICROANALYSIS OF THE MATRIX: The main element detected IS NICKEL (higher spectrum)

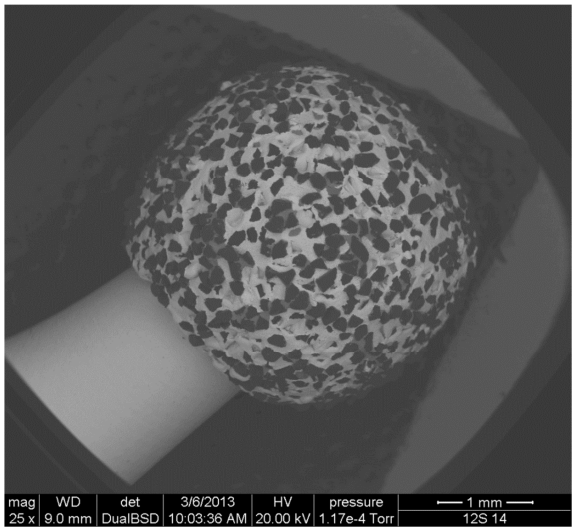
MICROANALYSIS OF THE STUCK: The main elements detected are GOLD, CARBON, OXYGEN (lower spectrum)

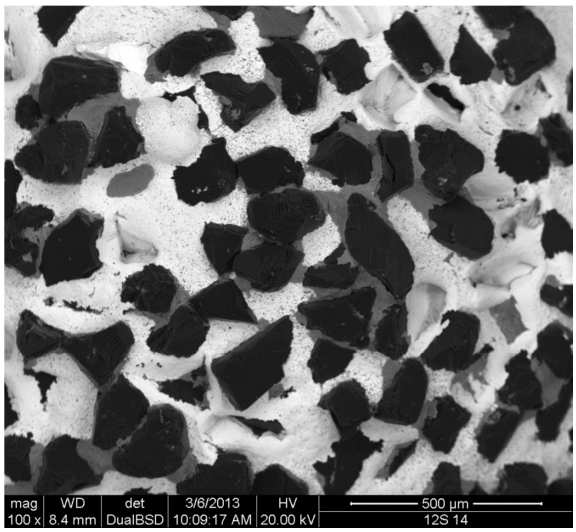


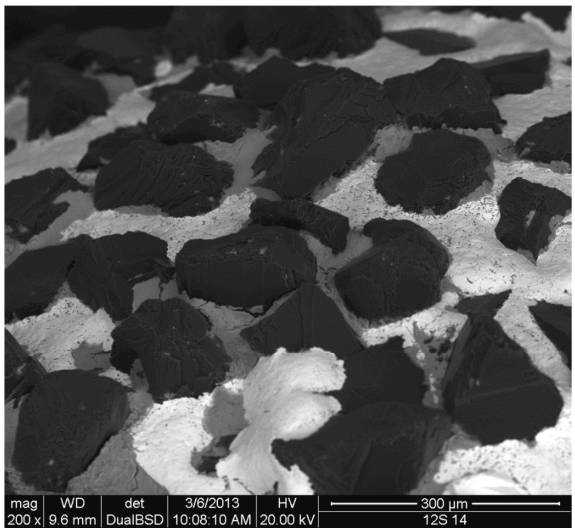
MICROANALYSIS OF THE STUCK: The main elements detected are IRON, CHROME, NICKEL (STEEL)

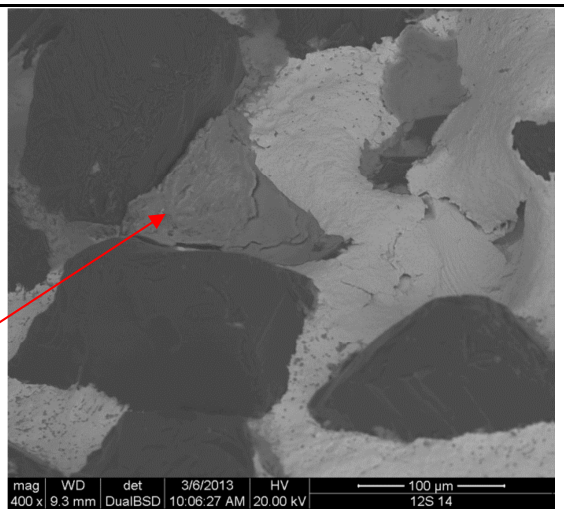
BICARJET® treated "stressed" Diamond Burr DS6 (n. 12-S-0014): the surface of the diamond burr does not appear to be altered. Small-scale particles are detected where fragments of diamond are missing. The total area is of 1.17% of the diamond. The particles have a varied chemical composition: calcium, phosphorus, oxygen (connective tissue residue), potassium, carbon, chlorine, sodium, and traces of other elements.

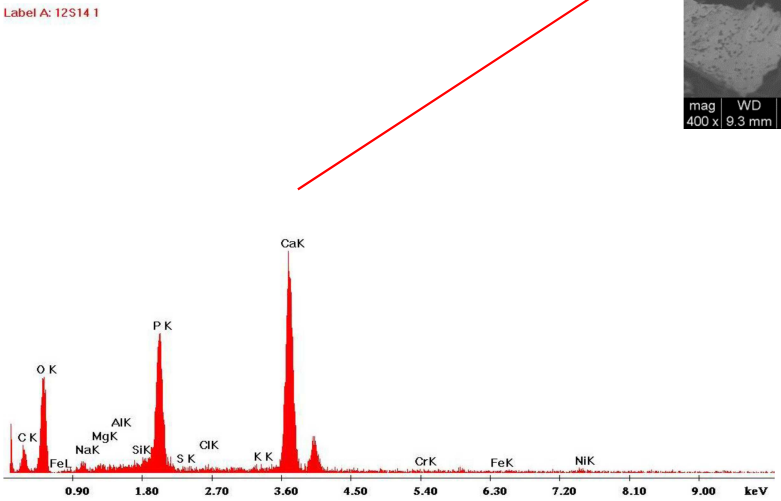


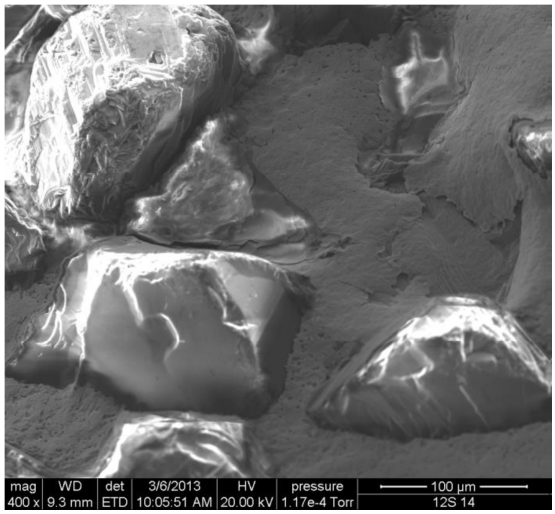












MICROANALYSIS OF GREY PARTICLES: The main elements detected are CALCIUM, PHOSPORUS, OXYGEN (comprising connective tissue residue), POTASSIUM, CHLORINE, CARBON AND SODIUM.

Discussion

The results obtained by the two treatments (STANDARD e BICARJET®) used for cleaning samples were quite different.

As regards the rosen burr and the craniotome, the STANDARD treatment contributed to the abrasion of the overall metallic surface of the instrument. The organic residue on the instrument found following normal clinical use was not removed. The BICARJET® treatment conserved almost entirely the metallic surface of both the "standard" and "stressed" samples. Moreover, no bone residues were found on the latter and the only traces of elements found may be attributed to the treatment stage where the plate was being removed, to contaminants, the saline solution, and sometimes even brass from the hose used to administer the MELTRON® solution.

As regards the diamond burr samples, the difference noted between the two may be attributed to the morphological characteristics of the sample. The surface of the diamond burr submitted to the STANDARD treatment does not seem altered except for loss of diamond fragments from the nickel matrix. The foreign particles detected on the instrument comprise of metallic contaminants and residue of saline solution. With the BICARJET® "standard" treatment, cleaning appears to be perfect while on the "stressed" samples connective tissue was noted among the diamond fragments. The latter phenomena may be related to the way the diamond's apex is shaped. Considering the morphology of the burr, the particle-size of the bicarbonate used (MELTRON® GG 500 µm) may be inadequate as it is not the correct size.

In normal clinical practice, the stress-rate applied here to the burr is never reached and represents an extreme study of the efficiency of MELTRON® saline solution.

Conclusions

The BICARJET® treatment removes organic residue without significantly altering the surface of the sample, contrary to accredited processes supplied by leading companies in the sector as well as the STANDARD cleaning treatment documented by the University of Trento and Regional Health Services as well as other. Rough surfaces produced by manual brushing increase the risk of embedded organic material. This, in turn, makes its removal even more critical because of an increase in related risks.

Based on the documented alteration of the instrument's surface, manual brushing, normally used in standard reprocessing processes, is inadvisable. A low-pressured jet of sodium bicarbonate is effective in cleaning surgical instruments guaranteeing effective removal of organic residue, minimal surface alterations, and reduction in related risk.

The results obtained guarantee higher safety standards in reusing surgical instruments. They also confirm that in-depth cleaning is possible by mechanical means while still conserving the instrument's surface, hence increasing the instrument's lifespan.

In addition, this technology rendered procedures considered standard until now obsolete.

We believe that electron microscopy, able to detect particles the size of one µm, makes this standard difficult to surpass, especially if results provided here will be confirmed on a larger scale during the course of this study.

Dr. Ilaria Toffanello

U.V.T.A. Director
Dr. Massimo Castoro