

Brand X scaler tips - Breakage study

REPORT N° A

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1/ Introduction

Following the market presence of Brand X scaler tip with an indication of Satelec compatibility, we have tested these tips on the Satelec test bench.

2/ Device observation

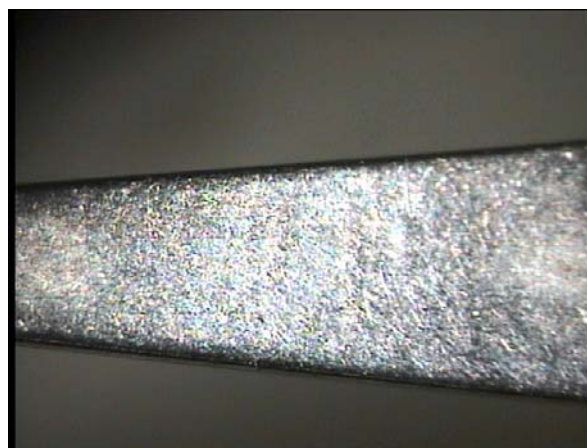
The Brand X tip tested, in appearance, is similar to the Satelec N°1 Tips, the profile configuration is very near to the Satelec tips.



Microscope inspection.



Brand X Tip

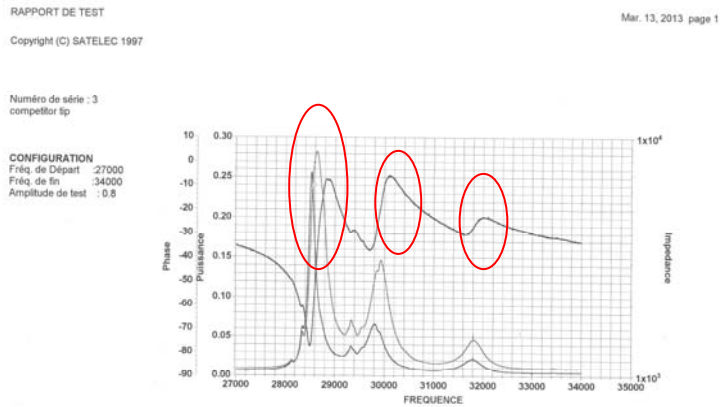


Satelec N°1 Tip

We can see that the metal aspect of the Brand X tip is not the same compared to the Satelec tip. Presence of tooling tracks on Brand X tip.

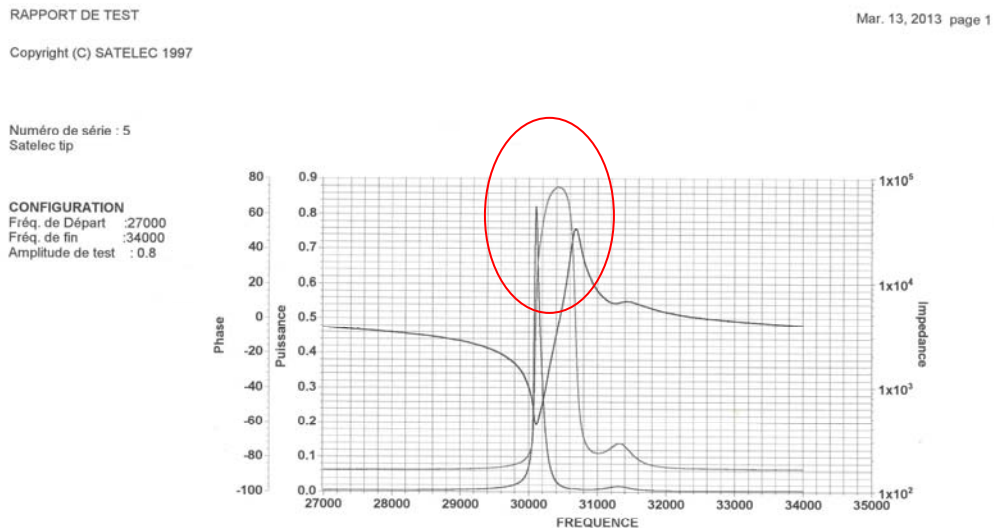
3/ Acoustic Test

The curve obtain with the Brand X tip is the following:



We can see multiresonance frequencies with the Brand X tip around the working frequency, located between 29 and 35khz (this test has been performed with the Satelec Newtron hand piece).

Curve obtained with the Satelec tip:



With the Satelec tips, we can see a single resonance frequency.

The presence of multiresonance frequencies, is a risk of tip breakage. The working frequency can jump on each resonance frequency.

4/ Functional tests

The Brand X tip is placed on the Satelec hand piece connected to the Satelec test bench (similar to our Satelec scaler generator). After 20 seconds, a breakage of the tip appears.

Before the test:



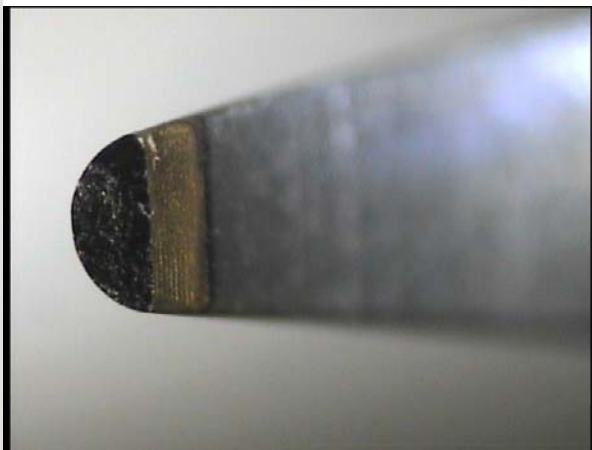
After 20 seconds of working:



We can see a tip breakage at 4 millimeters of the tip extremity (on the node of the ultrasonic wave).



Microscope visualization:



5/ Identification of the breakage cause

This breakage is certainly due to the multiresonance frequencies ; this tip is not adapted to a Satelec transducer and Satelec electronic power supply. The other explanation of the breakage is the presence of tooling tracks on the tip active surface.

6/ Conclusion

This test report shows us that it is imperative for a safe working to use Satelec Tips;

The Satelec tips are designed to work with Satelec Transducer and Satelec electronic only;

Multimode working can appear with Brand X tip used with Satelec transducer and Satelec electronic, leading the assembly to become dangerous for the patient and clinical application.