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Research and Development

Expert report (REPORT N° C)

Product : brand X tips

Expertise objective:

- Check the resistance of brand X tips to irrigators agents;
- identification of corroded parts and risk analysis.

Irrigator agents used :

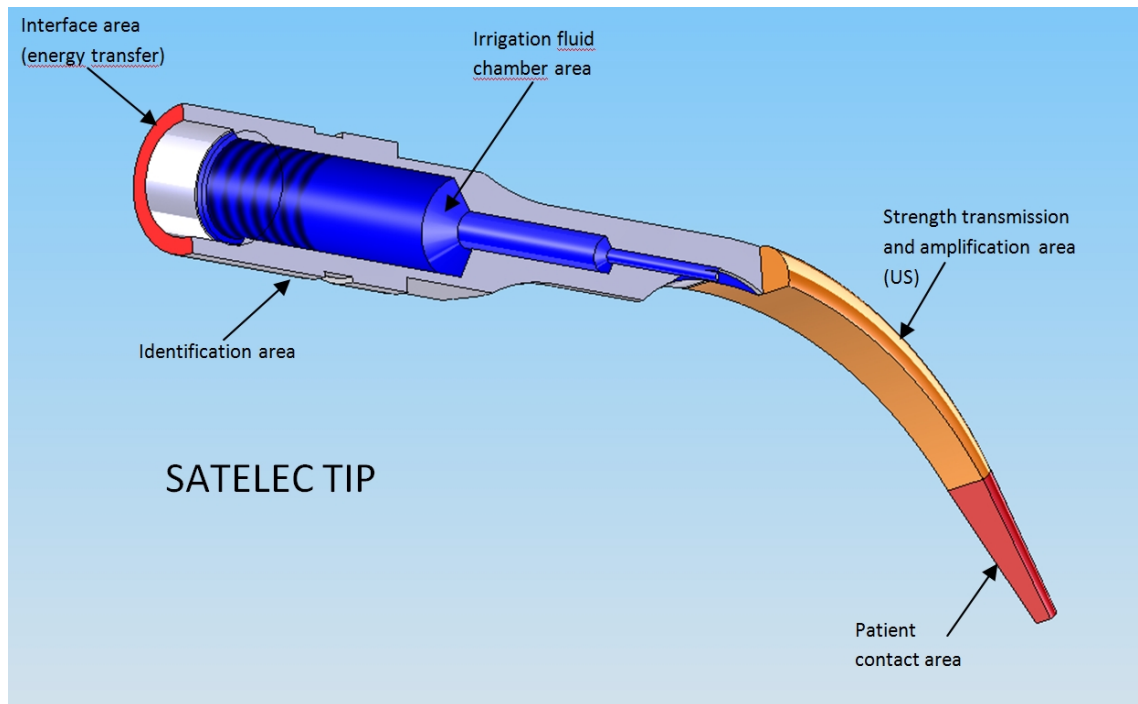
- Hypochlorite 2% ;

Expertise process :

- Visual inspection before first contact with irrigator agent;
- Visual inspection after immersion in irrigation products and photography of anomalies highlighted by area.

Risk analysis in association with functional areas of tips.

(example on standard tip. Every type have same functional areas)



Patient contact area :

This area in contact with patient produces the mechanical action on the treated part of the tooth. It transfers ultrasonic vibrations and thus makes the required effect, but can also contaminate the treated area due to contact and wetness of human tissues.

Therefore, the surface of this part is involved in the following risks:

- Erratic energy transfer may damage the treated surface of the patient's tooth (percussion effect, effect of excessive abrasion) due to inadequate form, a non-smooth surface or corroded;
- In opposite, ineffectiveness (no sharp edge, rapid wear) can induce longer use and lead to overheating of the tissue in contact.
- Lack of control of displacements due to the alteration of the shape of the tip inducing intensive application or otherwise insufficient application (not homogeneous);
- Transfer to the patient's body chemical residues produced by the corrosion of the steel used. These products are oxides and chlorides and depends on the action of the irrigator on the alloy steel of poor quality, and may be water soluble and therefore transmitted in all aqueous fluids (saliva, blood, ...)

Strength transmission and amplification area (US)

This zone is subjected to vibrations at 29000 Hz with amplitudes of 10 to 150 μ m (pp) in bending. The resistance of this zone to high frequency accelerations determines the non-breaking of tips, the risk of fatigue breaking being initiated by a weakness of the material.



Cracks and fissures in steel are the starting point of this type of failure. As such, the rugosity of the surface should be as low as possible.

Irrigation fluid chamber area

This volume transfers the product irrigating device to the treated area.

Any corrosion of the surface induces the same biological / chemical risks as the alteration of the surface of the end of tips :

Transfer to the patient's body chemical residues produced by the corrosion of the steel used. These products are oxides and chlorides and depends on the action of the irrigator on the alloy steel of poor quality, and may be water soluble and therefore transmitted in all aqueous fluids (saliva, blood, ...)

Interface area (Energy transfer)

This area is the interface with the transducer producing ultrasound vibrations.

The transfer of this energy assumes perfectly coplanar and smooth contact surfaces in relation to the transmitted energy. A precision better than one micron is essential.

The transmission losses due to bad quality of surfaces are manifested by the production of heat conducted by the tip to the patient, by the HP to the transducer and the skin of the practitioner's hand.

The numerous risks are mainly :

- Temperature increase of the tip in contact with the treated portion of the tooth;
- Erratic movements of the tip produced by the mismatching of the tip and of the HP and then percussion effect on the tooth;
- Increase of transducer temperature with risk of falling performance of the transducer and ultimately destruction of the engine;
- Vibration transferred to the hand of the practitioner.
- Heat transfer from the transducer to the external envelope upper to normalized level to the hand of the practitioner.

Identification area

This area is dedicated to marking the tips, not only from the mandatory point of view, but mainly gives information to select the appropriate power.

Using a tip on an inappropriate range can result in break during use in the patient's mouth.

Observations of functional areas of the brand X tips. :

Patient contact area :



All corroded

Strength transmission and amplification area (US)

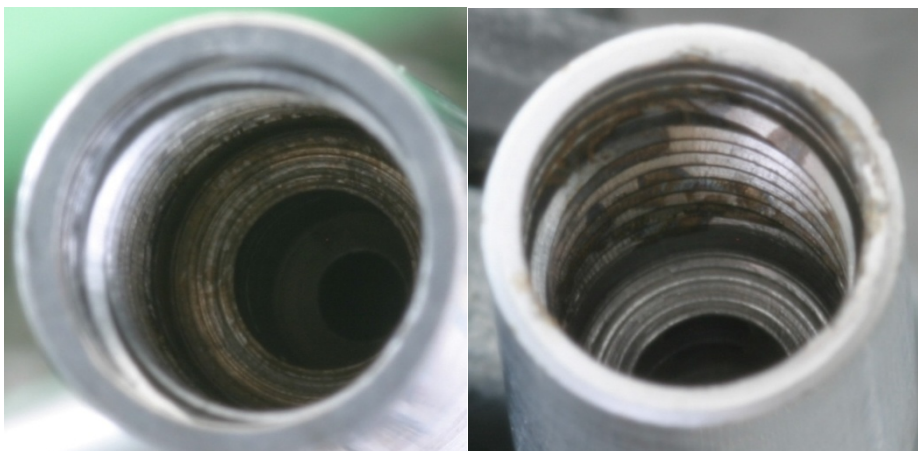


All corroded



Cracks, fissure and corrosion

Irrigation fluid chamber area



Interface area (Energy transfer)



Identification area



Not readable

Conclusion

Inspected tips does not guarantee the absence of risk for use with irrigator agents commonly used. Instead, they show that all functional areas involved in the application of the device are damaged and induce risks described.

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