

PLAY SAFE[®] triple



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Information Notice

The present booklet applies to the following mouthguards: **Playsafe triple • Playsafe triple light**

CE Marking explanation:

These made-to-measure mouthguards carry the CE marking to denote their compliance with the essential health and safety requirements of Regulation (EU) 2016/425 as 2nd Category PPE = Personal Protective Equipment against medium risks.

The performances of the mouthguard have been verified by RICOTEST, Notified Body nr. 0498, Via Tione 9, 37010 Pastrengo - Verona - Italy, on the basis of laboratory tests performed in accordance with an Internal Protocol. The mouthguard has passed the impact force transmission test performed with a flat impactor (2.5 Kg) striking the protector at 5J on the following areas: incisal surface, frontal buccal flange, and palatal flange.

The EU Declaration of Conformity is provided **with this Information Notice and/or at the following link:**
<https://www.erkodent.de/en/service-download/certificates/>

- ▶ **CE** The „CE“ means that the product satisfies the essential health and safety requirements of Regulation (EU) 2016/425 – Annex II
- ▶ **Erkodent Erich Kopp GmbH** -> Name of the manufacturer
- ▶ **Playsafe triple** or **Playsafe triple light** -> Produktbezeichnung (**article name and ref., see also packaging label**)
- ▶ **YYYY/MM** -> Date of manufacture (year/month), please refer to packaging label
- ▶ **LOT. XXXXX** -> Batch number, please refer to packaging label

Materials and manufacturing:

All materials used, as well as the applied processing techniques, have been chosen to meet the requirements of Regulation (EU) 2016/425. The materials used are not currently known to cause allergic reactions or sensitization.

Intended use:

Playsafe triple and Playsafetriple light are suited for any kind of sport. Triple light is suited in case of cramped oral situation. Playsafe triple and Playsafe triple light materials have a thickness of 5.5 and 4.1 mm each and are provided with a hard inter-layer comprising the whole guard.

Despite being a little bit harder than other models, they ensure increased protection.

When worn and used correctly, this mouthguard is meant to reduce the severity of injuries to the mouth caused by impacts when doing sport. The mouthguard must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can normally perform his/her sport activity whilst enjoying appropriate protection.

Fitting instructions:

Playsafe sports mouthguards, being individually fabricated, fit exactly onto the teeth, do not move and allow to breathe freely and to speak normally.

Every Playsafe mouthguard is fabricated by a trained person according to the Playsafe guidelines. You will get your Playsafe mouthguard in your dental practice. There, an impression of your upper and lower jaw will be taken. In the dental lab, the plaster model and the sports mouthguard will then be produced. The control of fit and handing over will again take place in the dental practice. Every Playsafe mouthguard can be further adjusted to changing proportions of teeth.

Free individualisation of a Playsafe:

25 colours are available for your Playsafe type: 1- bright red, 2- bright yellow, 3- bright blue, 4- bright green, 5- bright pink, 6- light blue, 7- transparent, 8- deep red, 9- dark blue, 10- maroon, 11- deep green, 12- pure white, 13- deep black, 14- gold, 15- silver, 16- camouflage, 17- lava, 18- tie-dye, 19- rainbow, 20- confetti, 21- zebra, 22- gold flakes, 23- silver flakes, 24- camouflage strip, 25- lava strip. The final user can compose his/her multi-coloured mouthguard with up to four colours (out of the colours 1 to 15).

For further information please check the Playsafe guidelines:

https://www.erkodent.de/wp-content/documents/products/Playfly_EN.pdf

Care, maintenance, storage:

Please refer to the Playsafeclean instructions enclosed with the Playsafre triple (Playsafe clean 07.2021).

To clean your mouthguard the best option would be to use the Oxydens Clean Set. For information on how to use it, please check our website.

<https://www.erkodent.de/en/products/thermoforming-foils-and-accessories/oxydens/>

Otherwise, take care of your equipment as per the procedure described below:

- 1- clean your mouthguard with soap and a toothbrush (**do not use toothpaste**)
- 2- wash it under fresh running water
- 3- dry the mouthguard with a paper towel and store it back in its box
- 4- prior to each use, rinse the mouthguard under running water.

When not in use, the mouthguard must be stored at room temperature. Do not use dryer or heating devices.

Avoid storing the mouthguard under heavy weights in order for it to keep its shape.

Do not expose the mouthguard to direct sunlight nor to extreme heat for lengthy periods of time.

Safety warnings and limitations:

- **No sports mouthguard can protect against all injuries.**
- Do not chew the mouthguard. If it is chewed and/or not used as intended, its effectiveness in terms of fit, protection and durability will be greatly reduced.
- Have the mouthguard replaced immediately if it shows signs of wear, cracks or splits or if there is any doubt about its condition.

Duration and disposal instructions:

The obsolescence of the mouthguard depends upon the regularity and severity of its use. When used and worn on a daily basis, these protectors should normally remain serviceable for 6 months. However, regardless its frequency of wear we strongly recommend to replace the mouthguard after 12 months from purchase date.

At the end of the mouthguard's useful life be sure to not discard it in the natural environment: please follow local/national environmental regulations. Further information regarding these regulations can be obtained from local authorities.