

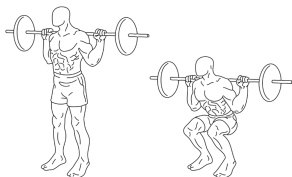
INSTRUCTIONS FOR USE
 Personal protective equipment: MOUTHGUARD FLUOBITE for DPI CATEGORY lifting weights 1
 - EU Regulation 2016/425

INTENDED USE
 Athletes lift weights / dumbbells are taken at the height of mental and physical effort to close her mouth violently clenching his teeth with each other and recalling energy useful to the movement itself. It is particularly indicated:

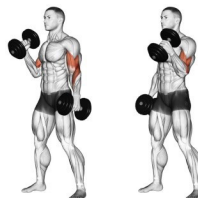
FLUOBITE®



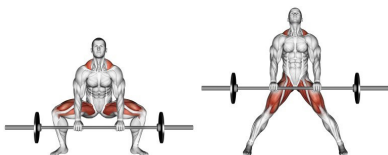
squat



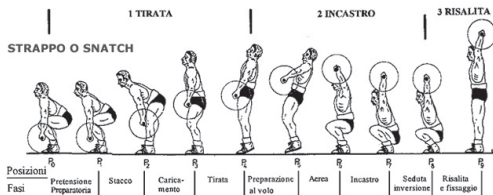
momentum



In the deadlift in the



the tear and curl up in the



mouthguards FLUOBITE They are intended to be used:

- in sports without contact with high physical demands (as per Table 1) limited to the disciplines of lifting weights;
- by persons (above the age of 18 included);
- to avoid that the teeth scheggino, during the window rubbing of the same.
- to protect the enamel, the outer fabric of the tooth, by mechanical trauma due to rubbing and impact between the teeth.

Hazard Class

During the research for the study of the product it was taken into account CLASSIFICATION OF SPORT ACCORDING to the impact CONTACT (ref. Cotin-Degani in the journal Value in 2010 sports publisher SEI) shown in Table 1:

Legislation

The legislation being considered for this device is as follows:

Code	Year	Title
Commission Regulation (EU) 2018/425 of the European Parliament and of the Council	March 9, 2016	On the personal protective equipment and repealing Council Directive 89/686 / EEC
Legislative Decree 9 September 2005, n. 206 and smi	September 6, 2005	www.codiceconsumo.it of the Consumer Code
Directive 1999/44 / EC as amended	May 25, 1999	Concerning certain aspects of the sale and guarantees of consumer goods
DIRECTIVE 2011/83 / EU	October 25, 2011	On consumer rights, amending Council Directive 93/13 / EEC and Directive 1999/44 / EC of the European Parliament and of the Council and repealing Council Directive 85/374 / EEC and Directive 97/7 / EC the European Parliament and of the Council
LEGISLATIVE DECREE 21 February 2014, n. 21	February 21, 2014	Implementation of Directive 2011/83 / EU on consumer rights, amending Council Directives 93/13 / EEC and 1999/44 / EC and repealing Directives 85/374 / EEC and 97/7 / EC
Regulation (EC) No. 1907/2006 as amended	December 18, 2006	Concerning the Registration, Evaluation, autorizzazione and Restriction of Chemicals (REACH), establish-constitutes a European Agency for chemicals.
Regulation (EC) No 1272/2008	December 18, 2008	Its classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548 / EEC and 1999/45 / EC, and amending Regulation (EC) No. 1907/2006
Regulation (EC) No. 1907/2006 (REACH)	18 dicembre 2006	concerning the Registration, Evaluation, autorizzazione and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45 / EC and repealing regulatory-fo (EEC), 793/93 and Regulation (EC) No. 1488/94 and Directive 76/759 / EEC and Commission Directives 91/155 / EEC, 93/67 / EEC, 93/105 / EC and 2000/21 / EC
UNI EN 1186-1	2003	Materials and articles in contact with foodstuffs - Plastics - Guide for the selection of conditions and test methods for overall migration
UNI EN 1186-3	2003	Materials and articles in contact with foodstuffs - Plastics - Test methods of global migration in aqueous food mulant by total immersion
UNI EN ISO 10993-10	2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Tab 1

Contact sports		Sport Contactless		
limited impact	Collision	physical requirements slight	physical requirements moderate	physical requirements high
Basketball	Boxing	Golf	Table tennis	Aerobics
Volleyball	Martial arts	Archery	Badminton	Tennis
Handball	Fight	Target shooting	Bowls	Athletics: launches
Baseball / Softball	Hockey	Shooting	Sailing	Athletics: Racing
Squash	Football	Gymnastic exercises sco-lasto bodyweight	Rhythmic and artistic gymnastics	I swim
Cycling	American Football	Twirling		Hiking
Dips	Rugby	Majorette		Boating
Athletics: jumps				Fencing
Gymnastics: tools				Weightlifting
Horse riding				
Skating				
Alpine skiing				
Nordic skiing				
Water ski				
Bob				
Karting				

Rating

On the basis of Annex I "CATEGORIES OF RISK OF PPE" of COOPIED Decree, 04/12/1992 n° 475 and Legislative Decree, 02/01/1997 n° 10, and COUNCIL DIRECTIVE 89/686 / EEC of 21 December 1989 and the EU REG 2016/425, the FLUOBITE in its two declinations only includes the following minimum risks contained in CATEGORY 1 set out below:

- a. superficial mechanical lesions;
 - b. contact with cleaning products slightly aggressive or prolonged contact with water;
 - c. contact with hot surfaces that do not exceed 50 ° C;
 - d. ocular lesions due to exposure to sunlight (different from injury due to the observation of the sun);
- ie. nature of atmospheric conditions are not extreme.




No PPE of complex design intended to protect from risks of death or serious injury, or from external shocks and permanent in nature and are therefore subject to the application of conformity assessment according to the internal production control (module A) referred to in Annex IV EU REG 2016/425

average life

The duration of the product based on experience is estimated to be one year. The duration may be limited depending on the manner of use and periodicity.


Packaging and instructions for disposal

The following provisions for the disposal of packaging materials and the DPI at the end of useful life.

Prodotto	Tipologia Materiali/numero	Symbol	Descrizione
Primary and carrying case	Polypropylene		Recycling
Primary Packaging Sales package	Polyethylene		Recycling
Protection device	Silicone		Undifferentiated not dump

*The card should be disposed of in the paper.

Warnings



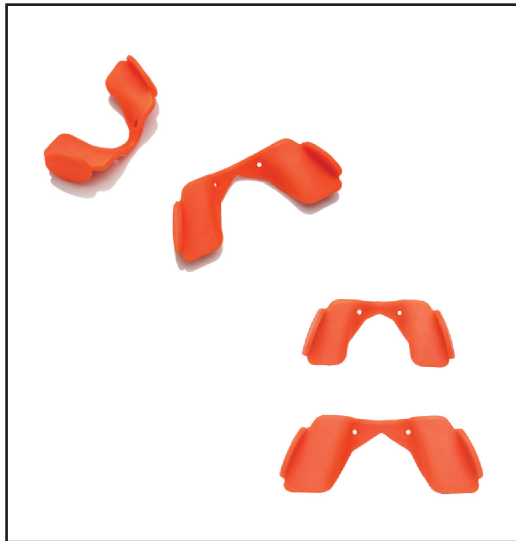
Use, maintain and use the mouth guard following these instructions. Failure to comply with these recommendations and instructions can seriously affect the protective effect of the mouthguard. PPE should be used for the entire duration of stress in order to correct effectiveness. The proper mouthguard use, is subject to information, training and especially at a doctor's user clinic.

They should not be used strong detergents but only those recommended in order to avoid damage to the product. This product can be damaged by certain chemicals (alcohol, acetone, Solvents, Etc.). Additional information should be obtained from the manufacturer. The mouthguard must be replaced whenever there is evidence damage and should be worn only if previously cleaned. Do not chew the mouthguard.


Replace your mouthguard regularly especially in case of frequent use.

Do not use:

- If you are under 18 years.
- If your teeth move.
- If your dentist told you that you have the articulation of temporomandibular joint disorders.
- If you have toothache, jaw pain, block the opening of the mouth or pain
- caused by bruxism or teeth grinding, or fatigue of masticatory muscles.
- for more than three months without consulting your dentist.
- when you sleep; it could be accidentally swallowed.



Instructions



Positioning:
The mouthguard is found to have an ergonomic shape such that the fitting sub lingual should be placed under the tongue.

Any inversions, whereas the tenderness of the material, however not involve injury to the user

With the mouthguard properly position does provide maximum comfort. Do not place the mouthpiece after use or during use, on dusty or dirty surfaces but put it back in its case when not worn. Never wear the mouthguard of another person and not allow others to use your own. Besides the risk of cross-infection, the protection may be impaired, and the mouthguard damaged beyond repair. Never wear the mouthguard with a mobile orthodontic appliance or with the removable dental prosthesis.

If you're making an orthodontic treatment with fixed brackets or invisible aligners can use the mouth guard after a year or during use, on dusty or dirty surfaces but put it back in its case when not worn. Never wear the mouthguard of another person and not allow others to use your own. Besides the risk of cross-infection, the protection may be impaired, and the mouthguard damaged beyond repair. Never wear the mouthguard with a mobile orthodontic appliance or with the removable dental prosthesis.

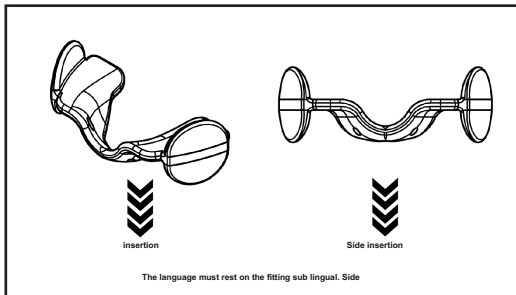
They should never be used for any other purpose, such as medical devices. Do not chew the mouthguard

Cleaning and storage
Rinse with cool water the mouthguard before each use. Use clean cold water (the temperature should not exceed 35 °) and a brush to wash and cleanse the mouthguard; after each use dry before storing it in the box. Do not use toothpastes, detergents or other cleaning materials. After each use, wash the mouthpiece and its housing with an antiseptic mouthwash. Do not expose the mouthguard to strong heat sources, for example, do not place in the dishwasher, in the washing machine, tumble, in the oven, on hot dashboards in cars and avoid exposure to direct sunlight.

The mouthguard must be kept in a box when it is not in use, in an environment with ideal temperature and not exposed to direct sunlight. When the extreme hot conditions are unavoidable, we suggest you keep your mouth guard in a container with water.

Always keep his mouthpiece in the housing when not in use. Write the name of the person wearing it on the cover with indelible ink. Check your mouthguard with a careful visual inspection is both manual before and after each use: The mouthguard should be replaced immediately in case of accidental punctures, cracks, cracks, fractures, or if the mouthpiece appears in poor condition. This mouthguard does not contain latex or materials that with current knowledge can cause allergic reactions or sensitization. Mouth guards are subjected to quality control using medical grade silicone that does not cause allergic reactions and has no perceptible odor or taste.

Towards insertion



Keep these instructions. Use for up to 30 minutes a day.

sharp teeth and particularly svilluppati masticatory muscles can greatly reduce the average life of PPE in use. The closed container and stored under ideal conditions has a shelf life of 2 years from the date of manufacture. Keep out of reach of children. If during use may arise nausea or dizziness, stop using. Do not use if you suffer from seizures.

FLUOBITE®



* See back of pack

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* See back of pack

