

ENGLISH - EN

Dental splints

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IMPORTANT INFORMATION.

READ THIS DOCUMENT CAREFULLY BEFORE USING THE PRODUCT.

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Page 1 of 7

FORM4.2-00018 V.00

Index

1. Product description	3
2. Intended use	3
3. Expected clinical benefit.....	3
4. Indications for use	3
5. Intended user and patient target group.....	3
6. Contraindications	3
7. Warnings.....	3
8. Precautions	4
9. Side effects	4
10. Cleaning and reuse	4
11. Important before using	4
12. Procedure	5
13. Storage and disposal of information	6
14. Information to be supplied to the patient.....	6
15. Incident reporting information	6
16. Legal compliance	6
17. Further information.....	6
18. Warranty Plan	6
19. Symbol description.....	7

1. Product description

Phibo Dental Splints are custom-made dental medical devices that are removably placed on the patient's upper or lower arch. These splints are designed under a doctor's prescription for a single patient.

These products are manufactured using 3D printing technology using a specific resin for dental use.

2. Intended use

Dental splints are intended to protect dental structures and reduce stress on the temporomandibular joint (TMJ) by physically separating the upper and lower teeth.

3. Expected clinical benefit

Dental splints provide clinical benefits by reducing bruxism symptoms, managing Temporomandibular Disorders (TMD), protecting against dental trauma and improving occlusal stability.

4. Indications for use

Dental splints are used to treat bruxism, TMD or dental trauma (e.g., avulsed or fractured teeth), as well as patients requiring occlusal stabilization.

5. Intended user and patient target group

Phibo Dental splints are intended for use by trained dental professionals. Proper training and expertise are essential to ensure effective application, adjustment, and patient education regarding splint use.

These devices cater to diverse patient age groups, from children and adolescents with trauma or orthodontic needs to adults managing TMD or bruxism.

6. Contraindications

Dental Splints have several contra-indications that must be considered before the prescription of the device:

- φ Presence of significant periodontal or dental infections that could worsen with the use of splints.
- φ Severe malocclusion or dental misalignment that prevents proper fitting.
- φ Allergy to splint materials, Phibo dental splints contains (meth)acrylate, therefore should not be used in patients with known hypersensitivity to these ingredients.
- φ Palatal plate with velar extension (spur).
- φ Patients with limited ability to maintain proper oral hygiene during splint use.

7. Warnings

Before the use of Dental Splints, some warnings must be considered to assure safety and performance of the device:

- φ DO NOT immerse the splint in water at a temperature higher than 45°C (113°F) due to the risk of deforming the device.
- φ Extended use of splints may lead to complications, such as ankylosis of the teeth.

- φ Inappropriate use or fitting of splints can exacerbate underlying conditions, including joint misalignment.

8. Precautions

During the use of Dental Splints is advisable to:

- φ Ensure the splint is properly fitted and adjusted by a trained professional.
- φ Educate patients on the importance of oral hygiene to prevent plaque accumulation under the splint.
- φ Periodically assess the fit and function of the splint.
- φ After any new dental work, ensure the fit of this splint is re-checked by your dental professional.
- φ In case of discomfort or excessive pressure, consult your dental professional for assessment.
- φ Monitor for signs of allergic reactions or material degradation.

9. Side effects

The use of Dental Splints may have adverse effects. The most commonly described adverse effects are:

- φ Temporary discomfort or soreness in the teeth or jaw muscles during the adaptation phase.
- φ Difficulty in speech or altered bite sensation.
- φ Potential for increased salivation or dry mouth depending on the splint design.
- φ Rare cases of irritation or sores may develop from parts rubbing on tissue.

10. Cleaning and reuse

This product is designed to be used usually during sleep. To ensure splint's hygiene, functionality, and longevity, please follow the instructions provided at Section 12. Procedure

Dental splints are designed individually for each patient, therefore could not be used for other individuals.

Product is sold non-sterile.

11. Important before using

The use and application of the Dental splints are beyond the manufacturer's control. The final adjust of the splint is user's responsibility and must inform patients about warnings, precautions and side effects of the use of the Dental Splints.

The patient is responsible for any damage that may be caused by the misuse of the splint, releasing Sineldent S.L.U. from liability for damages or losses resulting from improper handling or misuse.

Sineldent S.L.U documentation is periodically renewed according to the state of science and technology, please do not hesitate to contact us for additional information.

12. Procedure

Pack opening

Visually check that the packaging is not damaged, opened, or perforated. Check the data on the device's label to confirm that it matches with the splint selected for the designated patient. Open the package carefully, following the instructions on the package and placing it on a clean field.

Preliminary checks

First clean must be accurate, use a mild, non-abrasive soap or specialized dental appliance cleaner and rinse thoroughly. Some recommended cleaning agents include Dawn soap, Polident, Efferdent, a 3% peroxide solution, a 15% bleach solution, and mouthwash.

Check for proper fit with the patient. Insert the device into patient's mouth and instruct patient to carefully bite down to fully seat device. Trim away material that maybe impinging tissue or tooth surfaces. Advise patient of wear time and Daily and care maintenance (see below).

Daily care and maintenance

To ensure splint's hygiene, functionality, and longevity, the patient should follow these instructions:

- **Daily Cleaning:** Clean your splint daily before and after each use. Immediately after removing it, use warm water (not exceeding 45°C [113°F]) and soap to clean off saliva and any residue.
- Do not use dishwashers or boiling methods, as they may deform or damage the splint.
- **Use of cleaning agents:** For periodic cleaning of debris and maintenance, you can use any of the mild cleaning agents available commercially, designed for oral devices. If necessary, use a soft-bristled brush to clean the inside of your splint to remove debris. Some recommended cleaning agents include Dawn soap, Polident, Efferdent, a 3% peroxide solution, a 15% bleach solution, and mouthwash.
- DO NOT use abrasive cleaning agents (e.g., toothpaste) as they can shorten the life of your splint.
- DO NOT IMMERSE your splint in any liquid for more than 1 hour.
- Rinse Thoroughly: Always rinse the splint thoroughly with lukewarm water after cleaning to remove any residual cleaning solution.
- Be sure to dry your splint before storing it to prevent bacterial growth.
- Discard the cleaning solution after each use. Rinse the splint thoroughly before use.
- Do not eat or drink while wearing the splint. Exposure to hot liquids may affect its fit or shape.

- Regular Inspection: Check for cracks, discoloration, or wear. Consult your dentist if you notice any damage or fit issues.

13. Storage and disposal of information

Store in a clean, dust-free container away from direct sunlight to prevent material degradation. Avoid exposure to high temperatures or light to maintain structural integrity.

Dental parts must be discarded in an environmentally friendly manner in accordance with local regulations.

14. Information to be supplied to the patient

It is important that patients receive comprehensive details concerning contraindications, warnings, precautions and adverse effects associated with Phibo® dental splints.

15. Incident reporting information

Any incident related to Sineldent S.L.U products should be immediately reported to Sineldent S.L.U For detailed instructions, please access with your account at the Customer Center Platform (www.customercenter.Phibo.com) and consult the document **EN-MCC-0424001 Manual Customer Center**.

Serious incidents must also be reported to the local competent authority.

16. Legal compliance

Sineldent S.L.U complies with all the requirements established by European laws and guidelines relating to the manufacture and distribution of medical and health products.

17. Further information










For additional information or compatibility with other parts, please consult the Prosthodontic procedures available at Sineldent S.L.U website, at <https://Phibo.com/formacion-y-servicios/ifus/ifus-english/>. The Instructions of Use can also be requested printed at Sineldent S.L.U email atencionalcliente@sineldent.com.

18. Warranty Plan

The design of the product, its behavior and success of treatment are based on the indications mentioned above, and all those products that do not meet the indications described, and in, among others, are exempt from any warranty.

Dental splints have a warranty under the intended use of the product for 6 months.

19. Symbol description

SYMBOL	LEGEND
	<p>Medical Device manufacturer. Sinident S.L.U.</p> <p>P.I. San Cibrao núm. 22 32901 San Cibrao Das Viñas, Ourense Spain</p>
	<p>Date of manufacture.</p>
	<p>Batch number.</p>
	<p>Catalogue number / reference number.</p>
	<p>Do not use if the packaging is damaged and consult the instructions for use.</p>
	<p>For single use only.</p>
 <p>CUSTOM MADE PRODUCT</p>	<p>Custom made medical device.</p>
	<p>Consult electronic instructions for use.</p>
 <p>CAS: 75980-60-8</p>	<p>Contains hazardous substances</p>