

# USER MANUAL Lasal Dental Cushions

#### Feel comfortable at the dentist.

Dental Cushions are designed to ensure a comfortable base in the dental chair during treatment for patients with different needs and challenges. For use in dental clinics.



- Easy to adjust to patient and chair.
- Washable covers in different materials.
- Cushions for support of the head, neck, arms, legs, upper back, and lower back.
- Developed in cooperation with The Mun-H Centre in Odontology in Gothenburg, Sweden.
- Can minimize involuntary movements and tensity for the patient.
- 12 cushions in different shapes and sizes.



Cobi Rehab and Cobi Rehab suppliers comply with the UN conventions on child labour and forced labour as well as ILO 029, C132 and C182.

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# 1. Safety



### WARNING

Do not use Lasal Dental Cushions without thorough instruction from trained staff or from persons who have received instruction in the use of the positioning cushions. Improper use may injure the user.

Read this user manual carefully before using the Lasal Dental Cushions. Pay particular attention to Safety Instructions marked  $\triangle$ .

Cobi Rehab assumes no responsibility for any damage to the product nor for personal injury caused by incorrect use of the Lasal Dental Cushions.

Immediately contact Cobi Rehab if parts are damaged or missing. Never use your own spare parts.

Cobi Rehab cannot be held responsible for errors or accidents occurring after repairs are made without the written permission of Cobi Rehab.

### SAFETY INSTRUCTIONS

In this user manual, the symbol  $\underline{\Lambda}$  indicates a safety instruction. Follow safety instructions carefully.

Lasal Dental Cushions are intended for indoor use and must not be exposed to machine washing or strong chemicals.

Do not expose Lasal Dental Cushions to high temperatures, prolonged and intense sunlight, cold or other radiation, as it can affect the surface temperature and durability of the product.

Contact Cobi Rehab for all types of service and repair of the Lasal Dental Cushions.

# 2. Explanation of symbols

|   | Caution!   |  |  |  |
|---|--|--|--|--|
| CE  | Declaration of conformity, Medical Device<br>Regulation, EU 2017/745 |  |  |  |
| REF   | Cobi Catalogue number  |  |  |  |
| LOT   | Batch number   |  |  |  |
|   | Year of manufacture  |  |  |  |
| <b>**</b> *   | Manufacture  |  |  |  |
| MD  | Medical device, class I  |  |  |  |
| i   | Read manual  |  |  |  |
| CE-Label located at the side of the dental cushion.<br>See an example of an CE-label below. |  |  |  |  |



LASAL

Cushion/pude/kudde: Cover/överdrag PU Polyester with anti-bacterial coating. Filling: EPS beads Sanitary Cover/Hygiene överdrag : 100% PU polyester with Anti-bacterial coating Eco Jersey Cover: 52%Lenzin, 48% Tencel, FR

Cushion/pude/kudde : (0319-7501-000)

Sanitary/Hygiene Cover : (0319-7501-010)

Eco Jersey Cover : (0319-7501-015)



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### **3. General comments**

This user guide contains important information about the use of Lasal Dental Cushions and the patient group for the cushions. It also includes some specifications on the Lasal Dental Cushions.

The most recent version of this user guide can be found on our website. Check if the version you are reading now is the most recent.

If you need a user guide that is written in a larger font size, the product sheet is available in PDF format at cobirehab.com, which can be scaled up to the required font size.

You can always contact Cobi Rehab on telephone +45 7025 2522 or e-mail cobi@cobi.dk if you want more information about the Lasal Dental Cushions. Cobi Rehab reserves the right to change the product specifications without providing prior notice.

The UDI number of the Lasal Dental Cushions appears on the label, which is located on the side of each cushion.

Product safety notices and product recalls can be viewed on the website.

### 4. Use

Dental Cushions are designed to ensure a comfortable base in the dental chair during treatment for patients with different needs and challenges.

For patients with physical and mental challenges being seated or put down in a dental chair can cause discomfort, anxiety, and the restlessness. That is why Cobi Rehab has developed a dental cushion series.

Lasal Dental Cushions can be used alone or in combination to maximize the feeling of support, comfort and safety while visiting the dentist.

Dental fear can also be a reason for using Lasal Dental Cushion.

Regardless of the underlying reason, the aim is to avoid an uncomfortable position that may affect undesired muscle tension and thus complicating the dental treatment.

### 4.1 Contra indications

There are no contra indications associated with positioning with Lasal Dental Cushions.

#### Re-use

Please notice, that Lasal Dental Cushions must be thoroughly disinfected if they are to be used by another user. This is done to avoid crosscontamination. See the section on **Cleaning and maintenance**.

The various covers for Lasal Dental Cushions must be thoroughly washed or disinfected before switching to a new user.

# **5. About Lasal Dental Cushions**

Lasal Dental Cushions are developed in cooperation with The Mun-H Centre in Odontology in Gothenburg, Sweden.

Lasal Dental Cushions are available in multiple shapes and sizes. The combination of small beads of polystyrene in a smooth inner cushion contributes to each cushion adjusting to the body shape as well as the dental chair.

Lasal Dental Cushions are mouldable and therefore more stable than ordinary cushions. There are four cushions supporting the area around the head, one cushion in two sizes supporting arms and four cushions supporting e.g., legs and lower legs.

All cushions can be purchased with removable and washable hygiene or jersey covers. To prolong the durability of the cushions, Cobi Rehab always recommend using covers on the cushions.



U-Shaped Neck Cushions with hygiene cover.

#### Which cover to use?

For the working area around head and upper body we recommend dental cushions with hygiene cover which are washable at high temperatures and easy to disinfect.

Cushions for seat, legs and feet can be used with both covers. The advantage of a jersey cover in this area is that the surface of the cover ensures that it does not slip on the surface of the dental chair.



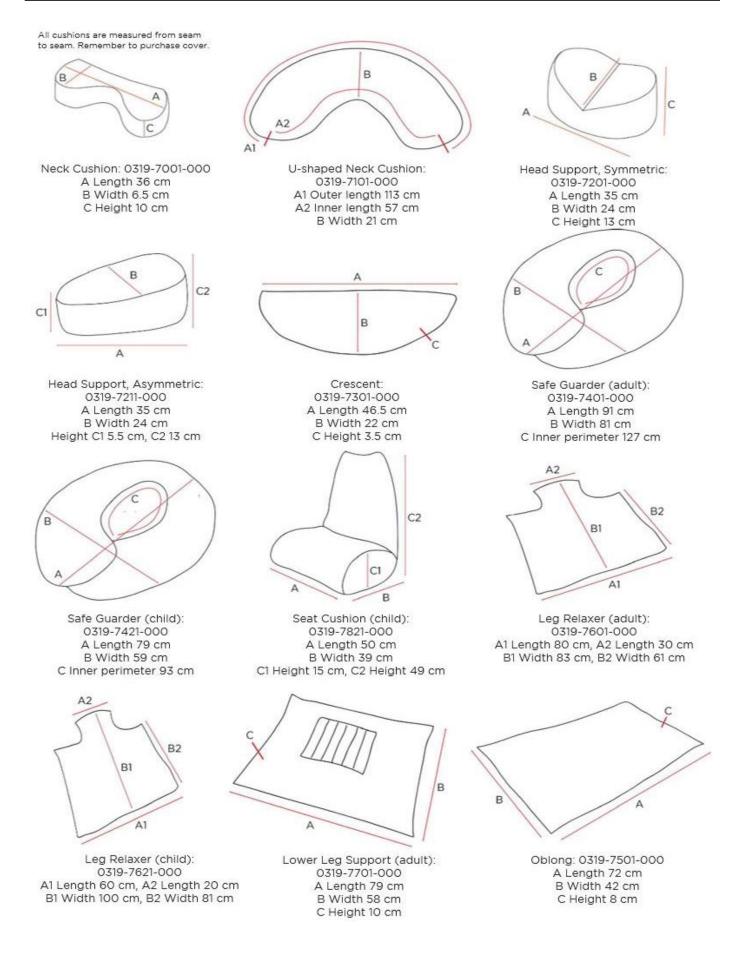
Safe Guarder (adult) with hygiene cover, Leg Relaxer (adult) with hygiene cover, oblong with



Safe Guarder (child) with hygiene cover, Crescent Cushion with hygiene cover, Seat Cushion (child) with jersey cover.



### 6. Lasal Dental Cushion overview



### 7. Get to know the different dental cushions

#### 7.1 Neck Cushion

A firm cushion placed under the patient's neck for support.

Neck Cushion: Order No 0319-7001-000.



Neck Cushion | Size 36 x 6.5 x 10 cm.

#### 7.2 U-shaped Neck Cushion

A mouldable cushion placed under the patient's neck to provide support and encircle.

U-shaped Neck Cushion: Order No 0319-7101-000.



U-shaped Neck Cushion | Size 113 x 57 x 21 cm.

#### 7.3 Symmetric Head Support

A full-bodied cushion available in two designs.

Symmetric cushion placed under the patient's head to lift and support the head in a desired position.

#### Symmetric Head Support:

Order No 0319-7201-000.



Symmetric Head Support | Size 35 x 24 x 13 cm.

#### 7.4 Asymmetric Head Support

Asymmetric cushion is placed under the patient's head to lift and support correction of the head control.

Asymmetric Head Support: Order No 0319-7211-000.



Asymmetric Head Support | Size 35 x 24 x 5.5/13 cm.

### 7.5 Crescent

A small mouldable cushion for minor support or lift. Crescent can also be combined with Neck Cushion/ U-shaped Cushion or Symmetric/Asymmetric Head Support.

Crescent: Order No 0319-7301-000.



Crescent | Size 46.5 x 22 x 3.5. cm

#### 7.6 Safe Guarder (adult)

A mouldable cushion placed with the narrow part behind neck/shoulder and with the cushion's "arms" embracing the patient around the shoulders, along both arms and closed with a grip band in front

Safe Guarder (adult): Order No 0319-7401-000.

#### 7.7 Safe Guarder (child)

Safe Guarder encircles and provides the child with a relaxed feeling. At the same time the Safe Guarder allows the child to relax in both arms from neck to fingertips without the arms falling to the sides.

Safe Guarder (child): Order No 0319-7421-000.

#### 7.8 Leg Relaxer (adult)

A mouldable cushion with the shape of a T. Placed under the patient's lower legs and feet with the T between the knees. Pulling the cushion further towards the patient minimizes the hip and the leg angle can reduce body tension and lower back pain.

Leg Relaxer can also be used to correct contractures of leg and hip.

The removable cover is equipped with a Support Band to (fasten the cushion to) avoid it from sliding down the chair.

Leg Relaxer (adult): Order No 0319-7601-000.



Safe Guarder adult | Size 91 x 81 x 127 cm.



Safe Guarder child | Size 79 x 59 x 93 cm.



Leg Relaxer | Size 80/30 x 83/61 cm.

### 7.9 Leg Relaxer (child)

A mouldable cushion with the shape of a T. Placed under the patient's lower legs and feet with the T between the knees. Pulling the cushion further towards the patient minimizes the hip and the leg angle can reduce body tension and lower back pain.

Leg Relaxer can also be used to correct contractures of leg and hip.

#### 7.10 Lower Leg Support

For adult patients. Used in combination with the Leg Relaxer. Place it on the top of the Leg Relaxer to stabilize lower legs, ankles, and feet to prevent them from sliding outwards.

Lower Leg Support: Order No 0319-7701-000.

#### 7.11 Oblong

Placed under the patient's knees. Oblong can also be used in combination with the Leg Relaxer and Lower Leg Support to provide extra support for the feet.

Oblong: Order No 0319-7501-000.



Leg Relaxer | Size 60/20 x 100/81 cm.



Lower Leg Support | Size 79 x 58 x 10 cm



Oblong | Size 72 x 42 x 8 cm.

#### 7.12 Seat Cushion

With the Seat Cushion a better position is obtained for the child patient. For a child the dental chair may seem big and in this situation the Seat Cushion helps stabilizing seat and back thus providing comfort and support for the child's entire back.

Seat Cushion: Order No 0319-7821-000.



Seat Cushion | Size 50 x 39 x 15/49 cm.

Wipe the cushions with a clean cloth wrung out in water with a mild detergent. The cushions must be completely dry before they are used again or put away.

#### **Desinfection and wash**

For surface disinfection of the cushions use disposable cloths with ethanol (e.g., Wet Wipe 70 %) or a chlorine product 1000-1200 ppm (e.g., Wet Wipe Chlorine Desinfection).

The hygiene cover is washable at 95° C and can be tumble dried. The jersey is washable at 60° C and can be tumble dried at low temperatures. Avoid rinsing products with solvent. Lasal Dental Cushions do not withstand machine washing. Machine washing will destroy the filling materials.

Lasal Dental Cushions without cover can be cleaned with a mild detergent or disinfected.

### 9. Storage

Do not expose the cushions to high temperatures, prolonged and intense sunlight, or other radiation.

#### 10.1 Long-time storage

For long-term storage (over three months) Lasal Dental Cushions must be stored in the dark and not exposed to strong odors or moisture.

The Positioning Cushions must be stored in plus temperatures, from  $0^{\circ}$ -  $40^{\circ}$  C.

# 10. Recycling and disposal

Dispose of products that are no longer in use in an environmentally safe manner. Contact your

local authority for further information on disposal.

### 11. Warranty

Cobi Rehab warrants that the Lasal Dental Cushions are without defects on delivery. If, against all expectations, the cushions are subject to deficiencies or defects on receipt, please contact Cobi Rehab immediately.

The warranty period for the Lasal Dental Cushions is one year from the date of purchase and covers manufacturing defects or defect on receipt. The invoice is your certificate of warranty.

The warranty does not apply to:

- products on which the serial number, batch number or the like have been removed or significantly damaged.

#### 11.1 Accidents

Report any incidents related to the use of Lasal Dental Cushions to Cobi Rehab.

#### **11.2 Expected service life**

After the expected service life, it is important that an overall assessment of the product is made before continued use.

After the expected service life, Cobi Rehab cannot guarantee the suitability and safety of the product, as Cobi Rehab has no control over how the product is used and wear and tear. - products which have been repaired by unauthorised personnel.

The warranty does not cover: - wearing parts.

This warranty does not apply when Cobi Rehab assesses that the Lasal Dental Cushions have been improperly used.

For damage caused by improper use, an invoice will be issued for both the service and the spare parts used.

The overall assessment of the product must be carried out by qualified professionals, and as a minimum, consideration must be given to how the product has been used, the condition of the product and its components.

Cobi Rehab can always make such an assessment.

### **12. Specifications**

| Filling materials             | Flame retardant EPS beads (Expanded Polystyrene)  |  |
|-------------------------------|---|--|
| Inner cover                   | PU-coated flame retardant polyester textile. Mold and fungus resistant.   |  |
| Hygiene cover                 | PU-coated flame retardant polyester textile. Mold and fungus resistant.   |  |
| Jersey cover                  | Single jersey OEKO-TEX (Lenzing/Tencil) with PU-coated back.<br>Waterproof. Flame retardant.                      |  |
| Cleaning                      | The cushion itself is not washable, but can be disinfected with e.g., Wet Wipes or cleaned with a mild detergent. |  |
| Washable covers               | Yes   |  |
| Storage                       | Do not expose the cushions to high temperatures, prolonged and<br>intense sunlight, or<br>other radiation.        |  |
| ISO classification            | ISO 09 07 06 - 02   |  |
| Expected Product Service Life | 3 years   |  |
| UDI-DI                        | 5740000100014N5   |  |
|                               |   |  |

You can always contact Cobi Rehab on +45 7025 2522 or cobi@cobi.dk for more information about Lasal Dental Cushions.

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# 13. Order

| Model                      | Color | Item number   |
|----------------------------|-------|---------------|
| Neck Cushion               |       | 0319-7001-000 |
| Hygiene cover              | Grey  | 0319-7001-010 |
| U-Shaped Neck Cushion      |       | 0319-7101-000 |
| Hygiene cover              | Grey  | 0319-7101-010 |
| Head Support, Asymmetric   |       | 0319-7201-000 |
| Hygiene cover              | Grey  | 0319-7201-010 |
| Head Support, Symmetric    |       | 0319-7211-000 |
| Hygiene cover              | Grey  | 0319-7211-010 |
| Crescent                   |       | 0319-7301-000 |
| Hygiene cover              | Grey  | 0319-7301-010 |
| Safe Guarder, adult        |       | 0319-7401-010 |
| Hygiene cover              | Grey  | 0319-7401-010 |
| Safe Guarder, child        |       | 0319-7421-000 |
| Hygiene cover              | Grey  | 0319-7421-010 |
| Oblong                     |       | 0319-7501-000 |
| Hygiene cover              | Grey  | 0319-7501-010 |
| Jersey Cover               | Grey  | 0319-7501-015 |
| Leg Relaxer, adult         |       | 0319-7601-015 |
| Hygiene cover              | Grey  | 0319-7601-010 |
| Jersey Cover               | Grey  | 0319-7601-015 |
| Leg Relaxer, child         |       | 0319-7621-000 |
| Hygiene cover              | Grey  | 0319-7621-010 |
| Jersey Cover               | Grey  | 0319-7612-015 |
| Support Band (Leg Relaxer) |       | 0319-7606-000 |
| Lower Leg Support, adult   |       | 0319-7701-000 |
| Hygiene cover              | Grey  | 0319-7701-010 |
| Jersey Cover               | Grey  | 0319-7701-015 |
| Seat Cushion, child        |       | 0319-7821-000 |
| Hygiene cover              | Grey  | 0319-7821-010 |
| Jersey Cover               | Grey  | 0319-7821-015 |





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