

**PHILIPS**

**ZOOM!**

WhiteSpeed  
Light-Accelerated  
Tooth Whitening  
Procedure Kit  
牙齿美白手术套装



Philips Zoom! WhiteSpeed  
Light-Accelerated  
Tooth Whitening Procedure Kit  
牙齿美白手术套装

**Instructions for use**  
使用说明书

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**English 6**  
简体中文 **22**

## Manufacturing information

Manufacturer:

Discus Dental, LLC

1700A South Baker Avenue

Ontario, CA 91761 United States of America

[www.philipsoralhealthcare.com](http://www.philipsoralhealthcare.com)

## Symbols



Consult instructions for use



Reference to enclosed or attached information



Caution



Keep away from sunlight, keep away from heat



Temperature limits



Manufacturer



Use by date



Batch code



Catalogue number



Do not re-use. This product is intended for use on a single patient during a single procedure.



Keep refrigerated

## Important information

Read and understand the information in these instructions for use provided with the Philips Zoom! Whitespeed Light-Accelerated Tooth Whitening Gel (whitening gel) prior to initiating whitening treatment.

The whitening gel must be removed from refrigeration and warmed to room temperature so it will thicken before it is applied to the patient's teeth. Either:

- Remove the syringe from refrigeration at least 6 hours before use (preferably the night before) or
- If removed just prior to use, place the syringe in a cup of hot water (49 °C) for 10 minutes. Remove the syringe from the water and wait 5 minutes before extruding gel.

## Conditions of use

This product is to be distributed to and used by dental professionals exclusively. This product is intended for use on healthy patients aged 18 years and older who have no underlying oral health issues, are not perio-involved and do not exhibit failing restorations.

## Contents

**Philips Zoom! WhiteSpeed Light Accelerated Tooth Whitening Procedure Kits (tooth whitening procedure kits) (for 1-patient use) include:**

- Light guide (1)\*
- Light guide instructions for use (1)

## 8 English

- Relief ACP oral care gel syringe, 2.4 ml (1)\*
- Relief ACP oral care gel instructions for use (1)
- Philips Zoom! WhiteSpeed Light-Accelerated Tooth Whitening Kit (tooth whitening kit) (1)

\* Refer registration information to the appendix.

### **Philips Zoom! WhiteSpeed Light-Accelerated Tooth Whitening Kit (1)\* includes:**

- Face bib (2)
- Gauze squares (6)
- Liquidam Dental Dam (Liquidam) Syringe, 2.9 g (1)
  - Liquidam needle point tip (metal tip) (1)
  - Liquidam black tip (plastic tip) (1)
- Cotton rolls (2)
- Surgical suction tip (1)
- IsoPrep retractor (retractor) (1)
- IsoPrep small retractor (small retractor) (1)\*\*
- Application brush (1)\*\*\*

\* Refer filing information to the appendix.

\*\*Only available in the 2-patient kit.

\*\*\*Non-medical device.

### **Packaged separately:**

- Philips Zoom! WhiteSpeed Light-Accelerated Tooth Whitening Gel (1)\*
  - Instructions for use (1)
  - 25 % Hydrogen Peroxide Whitening Gel syringe, 4.6 g (1)
  - Mixing tip (1)
- Philips Zoom! WhiteSpeed Whitening LED Accelerator (LED Accelerator)\*

\*Refer registration information to the appendix. Outside Philips Zoom! Tooth Whitening Procedure Kit offering.



## Product description

Philips Zoom! WhiteSpeed Light-Accelerated Tooth Whitening Procedure Kits are professional level (in-office) tooth whitening kits and are for single use only.

## Indications for use – candidate qualification

A screening exam is recommended to ensure the patient has no underlying oral health issues. You may want to treat existing issues before recommending this whitening treatment and disqualify any patient who is perio-involved, exhibits failing restorations or is otherwise in an unhealthy oral state.

## Patient's expectations

Set realistic expectations about potential results based on the oral exam and explain the following:

- Results vary by patient.
- Anatomy, calcifications, age, tooth condition, hygiene and starting shade affect the results.
- Teeth with yellow and brown stains will achieve the most noticeable results.
- Previous orthodontic treatments may cause teeth to whiten unevenly either due to residual resin remaining on the teeth or overpolishing upon removal.
- Crowns and other tooth-colored restorations will not whiten.
- Tooth-colored restorations may require replacement following whitening to maintain a uniform color.
- Tooth whitening may cause temporary dehydration of teeth resulting in white spots or striations. Uneven whitening will fade to normal within 2-7 days of the treatment.

## Pre-treatment for reducing tooth sensitivity

It is recommended to prescribe the following prior to the treatment:

- Treat with a desensitizing toothpaste with 5 %  $\text{KNO}_3$  twice a day for 14 days before the procedure.

- Nonsteroidal anti-inflammatory drug (NSAID) adhering to the respective drug's instructions for use 1 hour before the procedure.

## Warnings

- Do not place a composite/bonded restoration within seven days after whitening treatment to ensure color stability of the composite/bonded restoration and bond strength to enamel and dentin.
- Do not use tooth whitening gel on anesthetized teeth.
- Tooth whitening is not recommended when there are previous injuries in the gingival tissues.
- Avoid contact of whitening gel with eyes and soft tissue. If contact with eyes occurs, rinse eyes immediately with plenty of water and seek medical advice.
- Do not swallow the whitening gel.

## Intended use

Philips Zoom! WhiteSpeed Light-Accelerated Tooth Whitening Procedure Kits are for use with Philips Zoom! WhiteSpeed Light-Accelerated Tooth Whitening Gel and Philips Zoom! WhiteSpeed Whitening LED Accelerator for dental professional tooth whitening treatment. The tooth whitening procedure kit contents are intended to be used as follows.

Procedure Kit contents	Intended use
IsoPrep retractor	Moves the lips and cheeks away from the teeth, protecting the lips, cheeks and tongue from coming into contact with the whitening gel.
Face bib	Help protect the patient's face from the light source.

**Procedure Kit contents****Intended use**

Liquidam Dental Dam (gingival barrier material)	Used as an isolation material to prevent the whitening gel from contacting gingival tissues.
Cotton rolls	Separate the upper and lower vestibule during the procedure and help isolate the patient's lips from the teeth.
Gauze squares	Help isolate the patient's lip from the teeth and provide additional separation between the upper and lower vestibule.
Surgical suction tip	Remove excess liquid/saliva that may accumulate during the procedure.
Application brush	Apply whitening gel to the patient's teeth.
Light guide	An accessory to the LED Accelerator used to help align the head to a specified distance between the LED Accelerator and the patient.
Relief ACP oral care gel	Relieve discomfort from dentin sensitivity.

**Contraindications**

Philips Zoom! WhiteSpeed Light-Accelerated Tooth Whitening Gel is not for use on or by:

- Pregnant or lactating women.
- Patients currently being treated for a serious illness or disorder, e.g. immune compromised, AIDS, etc.
- Patients under 18 years of age.

## Possible side effects

- Teeth sensitivity or hypersensitivity.
- Gingival irritation or burn if Liquidam is not placed in accordance with the instructions in the tooth whitening procedure kit.

## Frequency of use

Philips Zoom! WhiteSpeed Light-Accelerated Tooth Whitening Gel is intended for a single-patient treatment. A single treatment typically consists of three to four 15-minute applications. A patient may be treated more than once at the discretion of the dental professional, allowing seven days between treatments.

## Safety

- Dental professional and patient need suitable protective covering and Zoom! protective eyewear.\*
- Avoid whitening gel contact with soft tissue and eyes.

\* Supplied with the LED Accelerator.

## First aid instructions

- Contact a Poison Information Center or medical doctor immediately if a large quantity (over 25 % of the syringe) is swallowed. Provide the ingredient label if possible. Do not induce vomiting. Immediately give a glass of water.
- If whitening gel gets into the eyes, hold the eyelids apart and flush the eyes continuously with running water for at least 15 minutes.
- If improper isolation leaves a patient's soft tissue exposed to light, administer a nonsteroidal anti-inflammatory drug (NSAIDs) adhering to the respective drug's instructions for use.

## Precautions

The whitening gel must be removed from refrigeration and warmed to room temperature so it will thicken before it is applied to the patient's teeth. Either:

- Remove the syringe from refrigeration at least 6 hours before use (preferably the night before) or

- If removed just prior to use, place the syringe in a cup of hot water (49 °C) for 10 minutes. Remove the syringe from the water and wait 5 minutes before extruding gel.

Note: Improper soft tissue isolation may result in irritation or burning of gingiva or swollen lips due to the LED Accelerator light coming into contact with tissue. Improper soft tissue isolation may also result in chemical burn due to whitening gel coming into contact with tissue.

Note: Wait one week after whitening to place restorations. Patients with porcelain fused to metal crowns, amalgams, lingual bars or implants will feel excessive heat.

## In-office whitening treatment

### Before the in-office whitening treatment

Complete diagnosis of patient, treat for sensitivity (see 'Pre-treatment for reducing tooth sensitivity') and fabricate trays\* prior to whitening treatment.

\* Outside Philips Zoom! Tooth Whitening Kit offering.

### In-office whitening treatment

- 1 Pumice teeth just prior to whitening.
- 2 Remove the light guide from the packaging and place it on the LED Accelerator.
- 3 Switch on the LED Accelerator using the power button located on the side of the power pack. When the light guide is attached, the display reads 'Guide Status-Guide Attached' followed by 'X of X Sessions'.
- 4 Place the surgical suction tip on the high vacuum suction.
- 5 Place the Zoom! protective eyewear on the patient.

Note: The retractor provided is necessary to ensure proper positioning of the LED Accelerator head and additional protection from light.

## 14 English



- 6** Insert the retractor at an angle, retracting one side at a time using a dental mirror to assist in placement.



Note: The retractor has been specifically engineered to work with the Philips Zoom! WhiteSpeed Light-Accelerated Tooth Whitening System (whitening system). Do not substitute.



- 7** Take a retracted 'before' photo using a matched shade tab.
- 8** Fully recline the patient.



- 9** Place cotton rolls in the center of the upper and lower vestibules. If the cotton rolls are too large, unfold the gauze and twist it like a cotton roll.

Note: Do not substitute gauze. The gauze provided has been tested and proven to provide superior protection.

- 10 Fully open the gauze squares and fold them into triangles. Place the apex of the triangle into the posterior cheek, tuck the balance of material into the cheek, tucking the ends between the cotton rolls and the retractor.



- 11 Carefully place one face bib around the retractor, one side at a time. Add an additional bib for heavy salivators.
- 12 Remove the Liquidam syringe from the packaging, twist to remove the cap and attach the metal tip.

Note: Exposed dentin and tissue should be covered by barrier material. Use the 'no pink' rule.



- 13 Dry soft tissue (failure to do so may create imperfect seal and allow whitening gel to migrate onto soft tissue) and begin by scalloping barrier material to CEJ area (gingival margins) on the upper teeth slightly overlapping enamel and interproximal spaces to form enamel seal.



## 16 English

- 14** Cure the application of Liquidam using a curing light.\*

\* Outside Philips Zoom! Tooth Whitening Procedure Kit offering.

Note: Liquidam can become warm upon curing. Move the light back and forth across the arch using a sweeping motion for about 10 seconds.

- 15** Change to the plastic tip. Fill in from the cotton roll to just formed line of Liquidam and cure. Be sure to cover all interproximal areas leaving no soft tissue exposed.

On the lower arch, apply Liquidam using the same method.

Use the tip of the syringe to press lightly on the application to ensure that it is completely cured. The material should be solid and have no give.

If necessary, cure the arch again for an additional 5 seconds.

The application should extend distal at least one tooth beyond the area receiving the whitening gel and should be 2 mm thick.

- 16** Remove the cap from the room temperature whitening gel syringe. Attach the mixing tip by aligning the marking and secure it by turning it one quarter turn clockwise. Using the brush provided, apply whitening gel to the patient's teeth (1-2 mm thick).

Use caution not to disturb the barrier material. Gingival irritation can occur with prolonged exposure to the whitening gel.

Note: A small air gap or bubbles in the syringe due to degassing of the whitening gel is normal. If the air gap is near the front of the syringe, purge until both sides of the barrel extrude gel.

Note: A slight yellow or pink coloring of the whitening gel is a normal occurrence from the manufacturing process. There is no impact on the peroxide content, other chemical properties, or performance of the whitening gel. It will not discolor the patient's teeth.

- 17** Once the whitening gel application is complete, raise the back of the chair so the patient is in a slightly reclined position (~45 degree angle) and able to swallow comfortably while maintaining light pressure on the bite block.



Note: The light guide is designed to ensure proper distance and alignment to maintain correct light exposure on the smile zone.



- 18** Slide the LED Accelerator into place next to the patient. The arm of the LED Accelerator should be movable, but stable. Position the LED Accelerator head by aligning the slots on the light guide with retractor.
- 19** Follow the prompts on the display panel to switch on the light and to activate the timer.

Once the light is on, a countdown is displayed. Light emits from the LED accelerator head to shine on the patient's teeth.

It is normal for the light to flicker for the first few seconds.

The LED Accelerator beeps once when three minutes of the session are remaining and beeps three times in the final three seconds of the 15-minute session.

When the session is finished, the light goes out and you hear a long beep.

Note: If a session must be interrupted, press the 'Pause' button. The remaining session time flashes on the display. To reactivate the session, press either the 'Pause' or 'Start' button.

- 20** Inform the patient that the progress of each session are tracked by four white lights on top of the LED Accelerator head. Each light indicates one quarter of a session.

Note: During each 15-minute session, make sure the patient has a means of communication (e.g. a bell) or do not leave the patient unattended.

- 21** After each session, gently pull the LED Accelerator away from the patient, taking care not to dislodge isolation material.

## 18 English

Note: At the end of each 15-minute session, the display indicates the number of remaining sessions left on the light guide. Press 'Start' to activate the light for the next session.

- 22** Carefully remove the whitening gel with the surgical suction tip and/or wipe the surface of enamel clean with damp gauze. Do not irrigate as the force of the water may pull the dam loose and saturate isolation materials.
- 23** Check the isolation materials to make sure 'no pink' tissue is visible. Replace or add isolation if needed.
- 24** Follow the same instructions as above for the remaining sessions.
- 25** When all sessions on a light guide are finished, the display reads 'Sessions Complete' for three seconds, followed by 'Guide Status - Replace Guide'. Detach the light guide from the IsoPrep retractor and pull the LED Accelerator away from the patient.

Note: For sensitive patients, lower the intensity of the LED Accelerator. However, please note this could result in a fourth 15-minute session.

Tip: If the patient notes tooth sensitivity, place Relief ACP (found in the tooth whitening procedure kit) on the lingual surface(s) for the remaining sessions. After the last session is complete, detach the light guide from the retractor and pull the LED Accelerator away from the patient. Suction or wipe the whitening gel from the teeth. Moisten gauze and cotton rolls and remove the isolation materials.

If barrier material remains interproximally, remove it with floss.



- 26** Reinsert the retractor and take a retracted 'after' photo with the lighter shade tab in place. Measure the shade change by counting the shade shift according to the value-ordered shade guide.\*

\* Outside Philips Zoom! Tooth Whitening Procedure Kit offering.

## Maximizing results

- Advise the patient not to consume coffee, tea, red wine and tobacco for two hours after the whitening treatment, until the salivary pellicle reforms on the teeth.
- All tooth whitening requires maintenance. The patient may choose to have the whitening treatment again or to use a maintenance product, depending on their habits.

## At home post care and maintenance

Philips Relief ACP oral care gel has been shown to decrease tooth sensitivity. Place Relief ACP oral care gel into fabricated trays and set on patient. Normal wear time is 30 minutes/time. Use Relief ACP twice a day until symptoms are relieved or as directed by your dental professional. For the best results, do not drink or eat for 30 minutes after application. See the Relief ACP oral gel instructions for use for complete instructions.

## At home whitening maintenance

24 hours after the whitening treatment, the patient may use Philips Zoom! NiteWhite or Philips Zoom! DayWhite Tooth Whitening Gel\* to maintain or further enhance their results. See the Philips Zoom! NiteWhite/DayWhite patient instructions for complete instructions.

\*Refer registration information to the appendix. Outside Philips Zoom! Tooth Whitening Procedure Kit offering.

## Storage instructions

The tooth whitening gel should be stored at 2 °C - 10 °C. The tooth whitening procedure kit should be stored at 15 °C - 25 °C.

Storage temperature outside the recommended ranges above will result in reduced product shelf life.

## Appendix

The medical device product registration information referenced within the IFU is listed as follows :

Product name: Tooth Whitening Gel

Model name: Philips Zoom! WhiteSpeed Light-Accelerated Tooth Whitening

Product specifications: 4.6g/syringe

Medical Device Registration Certificate No./Product Technical Requirement No. : GXZJ 2020170135

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Product name: Whitening LED Accelerator (including light guide)

Model and specification: Philips Zoom! WhiteSpeed

Medical Device Registration Certificate No./Product Technical Requirement No.: GXZJ2020170375

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Product name: Oral Care Gel

Model name: Relief ACP

Product specifications: (2.4g/syringe x1)/box, (2.4g/syringe x4)/box

Medical Device Registration Certificate No./Product Technical Requirement No.: GXZJ 2020170435

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Product name: Tooth Whitening Kit

Model name: Philips Zoom! WhiteSpeed Light-Accelerated

Product specifications: 1 set/box, 2 sets/box

Medical device filing certificate No./ Product Technical Requirement No.: GXB 20200672

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Product name: Tooth Whitening Gel

Model name:

Philips Zoom! DayWhite 6% Hydrogen Peroxide

Philips Zoom! DayWhite 9.5% Hydrogen Peroxide

Philips Zoom! NiteWhite 10% Carbamide Peroxide

Philips Zoom! NiteWhite 16% Carbamide Peroxide

Philips Zoom! NiteWhite 22% Carbamide Peroxide

Product specifications: (2.4ml/syringe x6 syringes)/box,  
(2.4ml/syringe x30 syringes)/box

Medical Device Registration Certificate No./Product Technical  
Requirement No.: GXZJ20203170310

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Registrant/manufacturer name: Discus Dental LLC.

Registrant/Manufacturer: 1700 A South Baker Avenue, Ontario, CA  
91761, United States Of America

Manufacturer address: 1700 A South Baker Avenue, Ontario, CA 91761,  
United States Of America

Registrant contact information: +1 (310) 845 8260

After-sales service agent: Philips (China) Investment Co., Ltd.

After-sales service agent address: Building A1, No. 718, Lingshi Road,  
Jing'an District, Shanghai

Contact information of after-sales service unit: 4008 800 008

Agent name: Philips (China) Investment Co., Ltd.

Agent address: Building A1, No. 718, Lingshi Road, Jing'an District,  
Shanghai

Agent contact information: 4008 800 008

Manufacturing date: see product label

Shelf-life: see product IFU

Transport conditions: see product IFU

## 22 简体中文

### 制造信息

制造商:

Discus Dental, LLC

1700A South Baker Avenue

Ontario, CA 91761 United States of America

[www.philipsoralhealthcare.com](http://www.philipsoralhealthcare.com)

符号



请查阅使用说明书



参考随附或附加的信息



注意



避免阳光直射，远离热源



温度极限



制造商



有效期



批号



## 目录号



请勿重复使用。本产品预期在单次手术中供单名患者使用。



## 冷藏保存

## 重要信息

在开始美白治疗之前，阅读并理解该使用说明书以及 Philips Zoom! WhiteSpeed Light-Accelerated 牙齿美白胶（美白凝胶）随附的使用说明书中的信息。

必须从冷藏过程中取出美白胶，并加热至室温，以便在涂抹到患者牙齿上之前变稠。或

或者：

- 使用前至少6小时（最好是前一天晚上）从冷藏过程中取出注射器或
- 如果在使用前刚刚取出，将注射器放入一杯49℃热水中10分钟。从水中取出注射器，等待5分钟，然后挤出凝胶。

## 使用条件

本产品仅供牙科专业人员分发和使用。其适用于18岁及以上的健康患者，这些患者没有潜在的口腔健康问题，不涉及围术期，也没有表现出修复体失败。

## 24 简体中文

### 内容物

**Philips Zoom! WhiteSpeed Light-Accelerated** 牙齿美白手术套装（牙齿美白手术套装）（一人份）包括：

- 导光器 (1)\*
- 导光器说明书 (1)
- Relief ACP 牙齿脱敏剂注射器，2.4mL (1) \*
- Relief ACP 牙齿脱敏剂使用说明书 (1)
- Philips Zoom! WhiteSpeed Light-Accelerated 牙齿美白工具包 (牙齿美白工具包) (1)

\* 注册信息详见附录

**Philips Zoom! WhiteSpeed Light-Accelerated** 牙齿美白工具包\* (1) 包括：

- 护面纸巾 (2)
- 方巾 (6)
- Liquidam 缝隙封闭糊剂 (Liquidam) 注射器，2.9g (1)
  - Liquidam 针头 (金属针头) (1)
  - Liquidam 黑色针头 (塑料针头) (1)
- 棉卷 (2)
- 吸唾管 (1)
- 牙科开口器 (开口器) (1)
- 牙科开口器 (小开口器) (1) \*\*
- 小刷 (1)\*\*\*

\* 备案信息详见附录

\*\* 仅在2人套装中提供

\*\*\* 非医疗仪器



### 单独包装:

- Philips Zoom! WhiteSpeed Light-Accelerated 牙齿美白胶 (1) \*
  - 使用说明 (1)
  - 25% 过氧化氢美白胶注射器, 4.6g (1)
  - 混合头 (1)
- Philips Zoom! WhiteSpeed 牙齿冷光漂白仪 (以下简称LED漂白仪)\*

\* 注册信息详见附录。不在Philips Zoom!牙齿美白手术套装中提供。

### 产品描述

Philips Zoom! WhiteSpeed Light-Accelerated 牙齿美白手术套装是专业级（诊室）牙齿美白手术套装，仅供单次使用。

### 适应症—适用人群

建议进行筛选检查，以确保患者没有潜在的口腔健康问题。在美白治疗之前应先治疗现有口腔健康问题，处于围术期的患者、显示修复体失败或处于不健康口腔状态的患者不应进行美白治疗。

### 患者期望

根据口腔检查对美白效果设定切合实际的期望，并解释说明以下内容：

- 美白效果因患者而异。
- 解剖结构、钙化、年龄、牙齿状况、卫生状况和起始颜色会影响美白结果。

## 26 简体中文

- 带有黄色和棕色色斑的牙齿将获得最明显的美白效果。
- 之前的正畸治疗可能会由于残留在牙齿的树脂或去除树脂时过度抛光而导致牙齿美白不均匀。
- 牙冠和其它牙色修复体将不会变白。
- 牙色修复体在变白后可能需要更换以保持均匀的颜色。
- 牙齿美白可能会导致牙齿暂时脱水，造成白色斑点或条纹。美白效果不均匀，使用2-7天即可恢复正常。

### 用于降低牙齿敏感性的预处理

建议在治疗前开具以下处方：

- 术前用含5% KNO<sub>3</sub>的脱敏牙膏治疗，每天两次，连续14天
- 术前1小时，按照相应药物的使用说明书服用非甾体抗炎药（NSAID）

### 警告

- 请勿在美白治疗后7天内放置复合体/粘接修复体，以确保复合体/粘接修复体的颜色稳定性以及与牙釉质和牙本质的粘接强度。
- 请勿对麻醉的牙齿使用牙齿美白胶。
- 如果牙龈组织之前已经受伤，不建议进行牙齿美白。
- 避免美白胶与眼睛和软组织接触。如果接触眼睛，请立即用大量水冲洗眼睛并就医。
- 不要吞咽美白胶。

## 预期用途

Philips Zoom! WhiteSpeed Light-Accelerated 牙齿美白手术套装与 Philips Zoom! WhiteSpeed Light-Accelerated 牙齿美白胶以及 Philips Zoom! WhiteSpeed 牙齿冷光漂白仪配合使用，用于专业牙科牙齿美白治疗。牙齿美白手术套装内的物品旨在按以下方式使用。

套装内容物	预期用途
牙科开口器	将唇部和脸颊远离牙齿，保护嘴唇、颊部和舌头不与美白胶接触。
护面纸巾	帮助保护患者面部免受光源照射。
Liquidam 缝隙封闭糊剂 牙龈屏障材料)	用作隔离材料，防止美白胶接触牙龈组织。
棉卷	用于在术中分离上下前庭，并将患者的唇部与牙齿隔开。
方巾	用于将患者的唇部与牙齿隔开，并额外分离上下前庭。
唾液管	清除术中可能积聚的多余液体/唾液。
小刷	将美白胶涂在患者的牙齿上。

## 28 简体中文

套装内容物	预期用途
导光器	LED漂白仪的附件，用于帮助将机头与LED漂白仪和患者之间的指定距离对齐。
Relief ACP 牙齿脱敏剂	Relieve discomfort from dentin sensitivity.

### 禁忌症

Philips Zoom! WhiteSpeed Light-Accelerated牙齿美白胶不能用于：

- 妊娠或哺乳期女性患者。
- 目前正在接受严重疾病或障碍（例如，免疫功能低下、AIDS等）治疗的患者。
- 18岁以下患者。

### 可能的副作用

- 牙齿过敏或超敏反应。
- 如果未按照牙齿美白手术套装中的说明放置Liquidam软组织隔离材料，则会引起牙龈刺激或灼伤。

### 使用频率

Philips Zoom! WhiteSpeed Light-Accelerated牙齿美白胶适用于单次治疗。单次治疗通常包括3至4次，每次涂抹15分钟。根据牙科专业人员的判断，患者可以接受不止一次治疗，两次治疗之间应间隔7天。

## 安全性

- 牙科专业人员和患者需佩戴合适的保护罩和Zoom! 护目镜\*。\*
- 避免美白胶接触软组织和眼睛。

\* 在LED漂白仪中提供

## 急救说明

- 如果吞咽大量美白胶（超过注射器的25%），请立即联系毒物信息中心或医生。如果可能，提供成分标签。请勿催吐。立即饮用一杯水。
- 如果美白胶进入眼睛，请扒开眼睑，并用自来水持续冲洗眼睛至少 15 分钟。
- 如果隔离不当使患者的软组织暴露在光线下，请遵守相应药物使用说明书服用非甾体类抗炎药（NSAID）。

## 注意事项

必须从冷藏过程中取出美白胶，并加热至室温，以便在涂抹到患者牙齿上之前变稠。或者：

- 使用前至少6小时（最好是前一天晚上）从冷藏过程中取出注射器或
- 如果在使用前刚刚取出，将注射器放入一杯49℃热水中10分钟。从水中取出注射器，等待5分钟，然后挤出凝胶。

**注意：** 由于WhiteSpeed漂白仪灯与组织接触，软组织隔离不当可能导致牙龈刺激或灼伤或唇部肿胀。软组织隔离不当还可能会由于美白胶与组织接触而导致化学烧伤。

注意：应在美白治疗一周后放置修复体。口内有金属烤瓷联冠、汞合金、舌杆或种植体的患者会感到过热。

## 诊室美白治疗

### 在诊所美白治疗之前

完成患者诊断，进行牙齿敏感治疗（请参见“用于降低牙齿敏感性的预处理”），并在美白治疗之前制作托盘\*。

不在 Philips Zoom! 牙齿美白工具包中提供。

### 诊室美白治疗

- 1 在美白之前用浮石粉处理牙齿。
- 2 从包装中取出导光器并将其放在LED漂白仪上。
- 3 使用位于电源组侧面的电源按钮打开LED漂白仪。连接导光器后，显示屏将显示“导光器状态 - 导光器已连接”，随后显示“第X个疗程，共X个疗程”。
- 4 将手术吸引头放在高真空吸引器上。
- 5 为患者佩戴Zoom! 护目镜。

注意：必须提供开口器，以确保LED漂白仪机头正确定位并提供额外的避光保护。



- 6 以一定角度插入开口器，使用牙镜一次牵开一侧，以辅助放置。



注意：开口器经过专门设计，可与Philips Zoom! WhiteSpeed Light-Accelerated美白系统配合使用。请勿使用替代品。



- 7 使用匹配的色条拍摄牵拉状态下的“治疗前”照片。
- 8 使患者完全躺卧。



- 9 将棉卷放在上下前庭的中心。如果棉卷太大，展开方巾并扭成棉卷的样子。

注意：请勿替代方巾。所提供的方巾已经过检验，并证明其能够提供更好的保护。

- 10 完全打开方纱并折叠成三角形。将三角形的顶点放入后脸颊，将剩余方巾推送至脸颊，固定在棉卷和开口器之间。

## 32 简体中文



- 11 小心地将面部围兜放在开口器周围，每次放置一侧的面部围兜。使用强吸唾器时应增加额外的面部围兜。
- 12 从包装中取出Liquidam注射器，拧开以取下盖子并连接金属头。

注意：暴露的牙本质和组织应被屏障材料覆盖。采用“无粉色暴露”规则。



- 13 使软组织干燥（否则可能会导致密封不完善并使美白胶接触软组织）并开始在上牙CEJ区域（牙龈缘）扇形涂抹封闭糊剂材料，材料略微重叠覆盖牙釉质和邻间隙以形成牙釉质封闭。



- 14 使用LED漂白仪\*固化涂抹的Liquidam。\*

\* 不在Philips Zoom!牙齿美白手术套装中提供。



注意：Liquidam 在固化后会变热。使用扫动动作在牙弓上来回移动灯光约10秒。

- 15 更换为塑料头。填满从棉卷到刚刚形成的Liquidam线之间的区域，然后进行固化。确保覆盖所有邻面区域，并且不暴露软组织。

在下牙弓上使用相同的方法涂抹Liquidam。

使用注射器的尖端轻轻按压涂抹部位，以确保其完全固化。该材料应为固体且无弹性。

如有必要，再次固化牙弓5秒。

涂抹部位应延伸到至少一个牙齿的远端，超出涂抹美白胶的区域，并且厚度应为2 mm。

- 16 从室温美白胶注射器上取下盖子。通过对齐标记来安装混合头，并顺时针旋转四分之一圈进行固定。使用提供的蓝色刷子，将美白胶涂在患者的牙齿上（1-2 mm厚）。使用时应小心避免破坏屏障材料。

长时间接触美白胶可能会出现牙龈刺激。

注意：由于美白胶脱气，注射器中存在小气隙或气泡属于正常现象。如果气隙靠近注射器前部，清除直至注射器筒的两侧均挤出凝胶。

注意：美白胶呈浅黄色或粉色是生产过程中的正常现象。对过氧化物含量、其他化学性质或美白胶的性能没有影响。其不会使患者牙齿变色。

- 17 涂抹美白胶后，抬高椅背，使患者处于略微倾斜的位置（约45度角），并能够舒适吞咽，同时保持对咬合块的轻微压力。

## 34 简体中文

注意：导光器设计用于确保适当距离和对齐，以维持微笑区域的正确曝光。



- 18 将LED漂白仪滑动至患者旁边。LED漂白仪臂应可以移动，但应具有稳定性。通过将导光器上的槽与开口器对齐来定位LED漂白仪机头。
- 19 按照显示面板上的提示打开灯并启动计时器。一旦灯亮起，将显示倒计时。从箭头所指的位置发出光。

LED冷光漂白仪机头发出的光照射在患者的牙齿上。

在最初几秒内，光线闪烁是正常现象。

当时间剩余3分钟时，LED漂白仪会发出一次蜂鸣声，并在15分钟治疗的最后3秒钟内发出三次蜂鸣声。治疗结束后，灯熄灭，您听到一声长蜂鸣声。

疗程结束后，灯熄灭，并发出一声长哔哔声。

注意：如果必须中断治疗，请按“暂停”按钮。剩余的治疗时间在显示屏上闪烁。要重新开始治疗，请按“暂停”或“开始”按钮。

- 20 告知患者LED漂白仪机头顶部的四个白灯可追踪每次治疗的进度。每个灯指示治疗的四分之一。

注意：在每个15分钟治疗过程中，确保与患者保持沟通（如铃声），或者避免让患者无人看管。

- 21 每个疗程后，轻轻将LED漂白仪拉离患者，注意不要移动隔离材料。

注意：在每个15分钟治疗结束时，显示屏将显示导光器上剩余的疗程数。按“开始”按钮，激活下一疗程的灯。

- 22 用手术吸引头小心去除美白胶和/或用湿方巾擦拭牙釉质表面。请勿进行冲洗，因为水的力量可能会导致 Liquidam 松动并使隔离材料吸水饱和。
- 23 检查隔离材料以确保“无粉色”组织暴露。如有需要，更换或增加隔离材料。
- 24 对于后续每个疗程，请同样遵循上述说明。
- 25 当导光器上的所有治疗结束时，显示屏将显示“治疗完成”三秒钟，然后显示“导光器状态-更换导光器”。将导光器与IsoPrep开口器分离，然后将LED漂白仪拉离患者。

注意：对于敏感患者，可以降低LED漂白仪的强度。但请注意，这可能会导致第四段15分钟的治疗。

提示：如果患者注意到牙齿敏感，在剩余疗程中，将 Relief ACP（在手术套装或患者术后护理和维护套装中找到）放置在舌面上。最后一段治疗完成后，将导光器与开口器分离，然后将LED漂白仪拉离患者。吸走或擦去牙齿表面的美白胶。浸湿方巾和棉卷，去除隔离材料。

如果邻间隙中残留屏障材料，请用牙线清除。

## 36 简体中文



26 重新放入开口器，并拍摄牵开状态下的“治疗后”照片，同时将较浅的色条放置到位。按照数值排序的比色板\*，通过计数色度变化测定色度变化。\*

\* 不在Philips Zoom!牙齿美白手术套装中提供。

### 最大化美白效果

- 建议患者在美白治疗后2小时内不要吸烟或饮用咖啡、茶、红酒，直到牙齿表面的唾液薄膜重新形成。
- 所有牙齿美白都需要维护。患者可以选择再次美白治疗或使用维持产品，具体取决于他们的习惯。

### 在家进行术后护理和维护

#### 减轻敏感

Philips Relief ACP牙齿脱敏剂已被证明可降低牙齿敏感性。将Relief ACP牙齿脱敏剂放入定制托盘中并放在患者口中。正常佩戴时间为每次30分钟，一天使用两次直至症状缓解或遵照牙医指导。为获得最佳美白效果，请勿在涂抹后30分钟内饮水或进食。有关完整说明，请参见Relief ACP牙齿脱敏剂使用说明书。

#### 在家进行美白维护

美白治疗后24小时，患者可以使用Philips Zoom! NiteWhite或Philips Zoom! DayWhite牙齿美白胶\*来维持

或进一步增强美白效果。有关完整说明，请参见Philips Zoom! NiteWhite/DayWhite的使用说明书。

\* 注册信息详见附录。不在Philips Zoom!牙齿美白手术套装中提供。

### 储存说明

牙齿美白胶应保存在2℃-10℃下。牙齿美白手术套装应保存在15 °C - 25 °C。

储存温度在上述建议范围以外将导致产品货架期缩短。

## 附录

本说明书中引用的医疗器械产品注册信息如下

产品名称： 牙齿美白胶

产品型号： Philips Zoom! WhiteSpeed Light-Accelerated Tooth Whitening

产品规格： 4.6g/支

医疗器械注册证编号/产品技术要求编号： 国械注进  
2020170135

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产品名称： 牙齿冷光漂白仪（包含导光器）

型号规格： Philips Zoom! WhiteSpeed

医疗器械注册证编号/产品技术要求编号： 国械注进  
2020170375

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产品名称： 脱敏剂

产品型号： Relief ACP

产品规格：（2.4克/支×1）/盒、（2.4克/支×4）/盒

医疗器械注册证编号/产品技术要求编号： 国械注进  
2020170435

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产品名称： 牙齿美白工具包

产品型号： Philips Zoom! WhiteSpeed Light-Accelerated

产品规格： 1套/盒、2套/盒

医疗器械备案证编号/产品技术要求编号： 国械备  
20200672

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产品名称： 牙齿美白胶

产品型号：

Philips Zoom! DayWhite 6% Hydrogen Peroxide

Philips Zoom! DayWhite 9.5% Hydrogen Peroxide

Philips Zoom! NiteWhite 10% Carbamide Peroxide

Philips Zoom! NiteWhite 16% Carbamide Peroxide

Philips Zoom! NiteWhite 22% Carbamide Peroxide

产品规格： (2.4ml/支X6 支)/盒、(2.4ml/支X30 支)/盒

医疗器械注册证编号/产品技术要求编号： 国械注进  
20203170310

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注册人/生产企业名称： Discus Dental LLC.

注册人/生产企业住所： 1700 A South Baker Avenue,  
Ontario, CA 91761, United States Of America

生产地址： 1700 A South Baker Avenue, Ontario, CA  
91761, United States Of America

注册人联系方式： +1 (310) 845 8260

售后服务单位： 飞利浦（中国）投资有限公司

售后服务单位地址： 上海市静安区灵石路718号A1幢

## 40 简体中文

售后服务单位联系方式：4008 800 008

代理人名称：飞利浦（中国）投资有限公司

代理人住所：上海市静安区灵石路718号A1幢

代理人联系方式：4008 800 008

生产日期：见产品标签

使用期限：见产品说明书

运输条件：见产品说明书



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