

IFU of UltraSeal XT™ hydro Pit and Fissure Sealant

Description:

UltraSeal XT hydro sealant is a 53% filled, light-cure, radiopaque, methacrylate-based, thixotropic resin sealant. It is hydrophilic and has a self-adhesive quality. UltraSeal XT hydro sealant chemistry provides the option of a visual verification for marginal retention with the use of a UV light, upon placement and at recall visits. The UV light is not included in the UltraSeal XT hydro sealant kit.

Accessories list

No.

Indications for Use:

Use UltraSeal XT hydro sealant for prophylactic sealing of pits and fissures.

Contraindications

Confirm that the patient will not be allergic to this product.  
For patients or users with allergy concerns, refer to common product allergen document available at [www.ultradent.com](http://www.ultradent.com).  
If allergic reaction is observed, rinse exposed area thoroughly with water and have the patient consult their physician.

Warnings and Precautions

- Resins can be sensitizing. Avoid repeated contact of uncured dental resin with skin, if contact occurs, thoroughly rinse skin. Do not use on patients with a known sensitivity to acrylates or other resins. If allergic reaction, dermatitis or rash develops, have patient consult their physician.
- Bring refrigerated products to room temperature before using.
- Redirect overhead light, or use UV protective light shield, to prevent premature polymerization.
- Re-cap immediately following use to avoid polymerization in syringe.
- Tips are single use. To avoid cross-contamination, do not re-use tips.

Directions for Use:

UltraSeal XT hydro sealant

- Preparation:
- 1) Attach Inspiral™ brush tip or Blue Micro tip to Ultra-Etch 35% etchant.
  - 2) Attach Inspiral brush tip to UltraSeal XT hydro sealant syringe. If desired, the Inspiral brush tip bristles length can be adjusted by grasping and moving inward or outward.
  - 3) Verify flow of all syringes prior to applying intraorally. If resistance is met, replace tip and re-check. Use only recommended tips.
  - 4) To prepare tooth prior to sealants use one of the following methods:
    - an air abrasion unit with appropriate particles
    - a thin diamond fissure/prep bur
    - air polishing prophylaxis system
    - Consepis Scrub antibacterial slurry
    - Prophyl paste
    - Flour of pumice
- NOTE: Use high magnification when cleaning grooves.
- 5) Apply etch to fissures for 20 seconds.
  - 6) Thoroughly rinse.
  - 7) Lightly air dry the tooth to remove visible moisture. Do not desiccate the tooth.

Placement:

- 1) Express a small drop of UltraSeal XT hydro sealant into the grooves. Work the resin down into the grooves with the brush tip.
  - 2) Light cure with VALO™ LED curing light on Standard Power for 10 seconds or 3 seconds on Xtra Power mode.
  - 3) Use an explorer to ensure pits and fissures are sealed and adjust occlusion if necessary.
- NOTE: As an option, a black light may be used for visual verification of marginal retention. Either the VALO curing light with the Black Light Lens specifically designed to filter for UV light, or a small black light, is available through Ultradent. For best results, redirect overhead dental light when using black light.

Processing

To avoid cross-contamination, wipe syringe with an intermediate level disinfectant between uses and use a disposable barrier sleeve. If a barrier sleeve is not used, syringe should be treated as single use.

Storage condition

The product should be stored at 2-27°C.

UltraSeal XT™ hydro Pit and Fissure Sealant

Manufactured by:  
Ultradent Products, Inc.  
505 West Ultradent Drive (10200 South)  
South Jordan, Utah 84095 USA  
Manufactured in the USA from globally sourced materials

**ULTRADENT**  
PRODUCTS, INC.

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Manufacturing date

Refer to product label

Shelf life

36 months

Explanation for the symbol on the label



Catalog number



Lot number



Do not re-use to avoid cross contamination



See instructions



Use by date



For professional use only



Manufacturer

Revised date:  
2022/5/20  
Registrant/Manufacturer: Ultradent Products, Inc.  
Address: 505 West 10200 South, South Jordan, UT 84095, USA  
Contact: +1-888-863-5883  
Agent/after-sales: Ultradent Products, China  
Address: Room 102, No.34 building, No.67 Gongye Dadao Bei Road, Haizhu District, Guangzhou 510250, P.R.China  
Contact: 020-84156506  
Registration number: 医疗器械注册证编号/产品技术要求编号: 国械注进20161272765  
Product name: Pit and Fissure Sealant and Conditioner Model/.

UltraSeal XT™ hydro Sealant 窝沟封闭剂说明书

产品描述

UltraSeal XT hydro Sealant 是一种浓度53%、具有影像学阳射性的甲基丙烯酸酯固化融化树脂封闭剂。该产品具有亲水型及自粘性的特点。UltraSeal XT hydro Sealant 窝沟封闭剂可以在首次及复诊时借助紫外光内眼验证边缘封闭强度。UltraSeal XT hydro Sealant 套装内不含紫外光产品。

配件清单

无。

预期用途

UltraSeal XT hydro Sealant 可用于预防性封闭齿科窝沟和裂隙。

禁忌症

使用前先确认患者对产品不过敏。  
对于有过敏顾虑的患者或用户，请参见 [www.ultradent.com](http://www.ultradent.com) 上的普通产品过敏原文件。如果观察到过敏反应，请用水彻底冲洗暴露区域并让患者就医。

警告和注意事项

- 树脂可能导致过敏。应避免未固化的牙科树脂与皮肤反复接触，如果发生接触，彻底冲洗皮肤。切勿用于已知对丙烯酸酯或其他树脂过敏的患者。如果出现过敏反应、皮炎或皮疹，请让患者就医。
- 日常使用时室温储存。批量存储时须冷藏。使用前须将冷藏产品恢复至室温。
- 移开头上的口腔灯，或使用紫外线防护服，以防止提前固化。
- 使用后盖回盖子，防止输送器中的产品固化。
- 输送头为一次性使用产品。为了避免交叉污染，切勿重复使用输送头。

操作说明

UltraSeal XT hydro Sealant 窝沟封闭剂

准备：

- 1) 在Ultra-Etch 35% 酸性剂上连接Inspiral™ 螺旋毛刷输送头或蓝色微型输送头。
- 2) 在UltraSeal XT hydro Sealant 窝沟封闭剂上连接Inspiral 螺旋毛刷输送头。如有需要，可抓握刷毛调节毛刷长度。
- 3) 在口腔内使用前检查输送头出液是否顺畅。如遇到阻力，更换输送头并重新检查。请使用推荐输送头。
- 4) 使用窝沟封闭剂之前，请使用以下任意方法备牙：
  - 具备适当颗粒的空气研磨装置
  - 金刚砂细牙钻
  - 抛光手机
  - Consepis Scrub清洁膏
  - 抛光膏
  - 轻石粉
- 注：清洁窝沟深处时，请使用高转速。
- 5) 涂抹酸性剂20秒。
- 注：裂钻和空气研磨装置是去除无釉柱釉质的唯一备牙方法。其它情况下的备牙需要酸性30秒。
- 6) 彻底冲洗。
- 7) 轻轻吹干牙齿去除为堆积凝聚的水分。请勿过度干燥牙齿。

放置：

- 1) 在窝沟深处中滴一小滴 UltraSeal XT hydro Sealant 窝沟封闭剂。用毛刷头使树脂向下进入到深处中。
  - 2) 使用VALO™ 固化灯标准模式光固化10秒或超强模式光固化3秒。
  - 3) 用探针检查确保窝沟和裂缝密封完好，并在必要时调整咬合。
- 注：亦可使用紫外灯对密封完整性进行视觉验证。皓齿公司的VALO光固化机有配专门过滤紫外光的黑光镜头，或者选择皓齿公司的小型紫外灯。为了获得最佳效果，请在使用紫外灯时移开口腔灯。

处理

为避免交叉污染，请在使用时隔用中級消毒劑擦拭注射器，并且使用一次性保护套。若未使用保护套，则应将输送器视为一次性使用。

储存条件

产品应在2-27°C储存。

生产日期

请见产品标签

使用期限

36个月

标签所用符号说明



目录号



批号



切勿再使用，以免交叉感染



参阅说明书



有效期



仅用于专业用途



制造商

注册人/生产企业名称: Ultradent Products, Inc. 美国皓齿制品有限公司  
注册人住所/生产地址: 505 West 10200 South, South Jordan, UT 84095, USA  
联系方式: +1-888-863-5883  
代理人/售后服务单位: 广州市皓齿登医疗器械有限公司  
住所: 广州市海珠区工业大道北路67号34号楼首层自编102房  
联系方式: 020-84156506  
医疗器械注册证编号/产品技术要求编号: 国械注进20161272765  
产品名称: 窝沟封闭剂  
型号规格: /.