

**产品描述**

Ultradent陶瓷酸蚀剂是一种含有氢氟酸凝胶的缓冲液,主要用于口腔内外的陶瓷酸蚀。

Ultradent预处理剂是一种单一组份的溶液,应用于酸蚀后陶瓷的粘接前处理。

**适用范围/预期用途**

该产品适用于口腔内外的陶瓷酸蚀和酸蚀后陶瓷的粘接前处理。

**禁忌症**

使用前,确认病患对本产品不会过敏。

**重要提示:**挥发的氢氟酸会刺激呼吸道,长期吸入会导致呼吸道损伤。Ultradent Porcelain Etch是一种缓释凝胶,其独特的配方能最大程度减轻相关损伤。必须严格按说明书,以确保清除所有有害物质。树脂粘接预备中,硅烷处理剂(Silane)用于酸蚀后的粘接。如果按照注意事项妥善操作,即可安全酸蚀口腔内陶瓷面,并按下列步骤粘接:

**操作步骤**

1. 用高速金刚砂磨头修复瓷面。如果之前进行过修复,务必去掉原有的复合材料,露出新鲜的瓷面。
2. 从注射器上拧下鲁尔锁帽。用手掌握住注射器以求实现最精准的控制。
3. 用Black Micro输送头(图1)涂抹一滴或一层EtchArrest酸蚀保护剂/中和剂,以实现邻近组织和修复体的隔离/保护。还可选择橡皮障(DermaDam)和橡皮障封闭剂(OraSeal)等隔离方式。
4. 在注射器上拧紧Inspiral螺旋毛刷输送头。Inspiral螺旋毛刷输送头能精确控制流量。
5. 涂抹前在混合器皿中挤出少量酸蚀剂,确保流量均匀并熟悉流量大小。如果遇到阻力,切勿继续。更换新的输送头,在患者身上使用前再次测试。立即按照政府法规)处理换下的输送头,以避免接触。
6. 用Inspiral螺旋毛刷输送头在预备后的瓷面(图2)上均匀涂布Porcelain Etch。酸蚀陶瓷90秒(注:图3和图4显示电子显微镜扫描前后的状况)。
7. 助手应在牙医涂抹Porcelain Etch时将吸唾器靠近陶瓷面。这样做可以确保酸液与陶瓷面反应(90秒)时吸除任何刺激性蒸汽。为中和Porcelain Etch,将Etch/Arrest与酸蚀剂混合,直至酸蚀剂的琥珀色逐渐消退。
8. 用吸唾器靠近表面吸走中和完毕的酸液,然后喷水冲洗。彻底冲洗并干燥。陶瓷面应为磨砂状,否则重复酸蚀步骤。
9. 使用Ultra-Etch处理5秒,以去除由氢氟酸酸蚀形成的硅盐和碎屑。冲洗并吹干。
10. 用Mini毛刷输送头涂抹硅烷处理剂,自然风干60秒。60秒后若仍未完全干燥,则用无油空气吹干。
11. 按照产品说明书放置粘树脂。

**重要提示:**测试显示陶瓷面酸蚀后使用Ultradent Silane硅烷处理剂,并按照以下步骤使用Peak Universal Bond通用粘剂,即可实现最佳粘结果。用Mini毛刷输送头在陶瓷表面涂抹硅烷。在陶瓷表面小幅轻刷硅烷60秒。吹干后继续涂抹Peak Universal Bond。

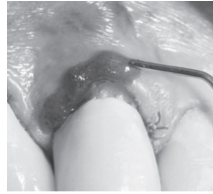


图1 在邻近牙齿表面的软组织上涂抹保护性EtchArrest涂层。

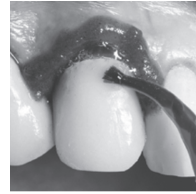


图2 在预备后的陶瓷面上小心地均匀涂抹Ultradent Porcelain Etch涂层。

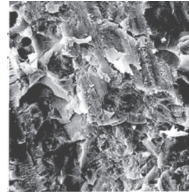


图3 电子显微镜扫描经过金刚砂抛光的瓷面。

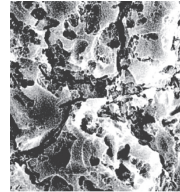


图4 注意:用Porcelain Etch酸蚀90秒后增加的沟槽和表面积。

**警告**

1. 化学品过几小时可能在尖端凝固。为避免堵塞,每次使用后须拧下输送头,盖回鲁尔锁帽。在口腔内涂抹前必须检查出液是否顺畅。如果遇到阻力,更换输送头并重新检查。以上不适用于双管式输送器及混合输送头。
2. 医生,助手和患者必须带上护目镜。
3. 不用时重新盖上鲁尔锁帽。输送头为一次性使用。
4. 建议使用Ultradent Syringe Covers保护罩,以防止交叉污染。
5. 处理或使用本产品时,临床医生和患者必须戴上带有侧罩的防护眼镜。

**注意事项**

1. 治疗前请先详细说明、注意事项和化学品安全技术说明书,谨遵本嘱使用。
2. 仅限专业人员使用。
3. 请避免置于光照或高温处
4. 避免皮肤触碰到树脂
5. 隔离强化学物质于治疗区域内。
6. 在口内使用之前,请先测试材料能否从注射器及输送头中顺利流出
7. 不可用力按压注射器推杆

关于产品的安全技术说明书请登录我们的网站查阅:www.ultradent.com

在Ultradent的注射筒上都标有1个字母和3个数字组成的有效期。其中字母表示生产批次,3个数字表示有效期。前2个数字表示月份,第3个数字表示年份的最后一位数字。

**运输和储存条件**

常温储存。

**生产日期和使用期限**

请见产品标签。

**标签所用符号解释**

参阅说明书



有效期



仅用于专业用途



切勿再使用,以免交叉感染



批号



回收



目录号



制造商

**说明书修订日期**

2020年6月

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  
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20162632247  
产品名称:陶瓷酸蚀剂  
型号规格:405, 406, 410 (具体见下表)

型号	描述	包装
406	陶瓷酸蚀剂迷你装	2×1.2mL
405	陶瓷酸蚀剂	2×1.2mL(陶瓷酸蚀剂)
		2×1.2mL(硅烷处理剂)
		20个黑色迷你毛刷输送头
	20个Inspiral螺旋毛刷输送头	
410	硅烷处理剂迷你装	2×1.2mL

**Description:**

Ultradent Porcelain Etch is a buffered, gelled hydrofluoric acid to be judiciously used for intraoral or extraoral etching of porcelain. Ultradent Silane is a mono-component solution for application to porcelain following etching with Porcelain Etch.

**Indications:**

Porcelain etch intends for etching the porcelain material intraorally and extraorally. It is also used for pretreating the porcelain before bonding.

**Contraindications:**

Confirm that patient has no known allergies to treatment materials.

**Important Note:** Hydrofluoric acid gives off a vapor that irritates respiratory passageways and on a chronic basis can damage them. Ultradent Porcelain Etch is buffered, gelled, and dispensed in a way that minimizes these problems. Instructions must be followed to ensure removal of any harmful material. Silane is for bonding after etching in preparation for bonding resin. If proper precautions are followed, porcelain may be safely etched intraorally for bonding as follows:

**Procedure:**

1. Freshen the porcelain surface to be repaired with a high speed diamond bur. If a previous repair is present, remove all old composite to fresh porcelain surface.
2. Remove luer lock caps from syringes. For optimum control, hold syringes in the palm of the hand.
3. Isolate/protect adjacent tissues and restorations by applying a bead or layer of EtchArrest acid barrier/neutralizer medium with the Black Micro tip (Fig. 1). An alternative isolation is rubber dam(DermaDam) and rubber dam sealant (OraSeal).
4. Twist an Inspirial Brush tip securely onto syringe. The Inspirial Brush tip ensures controlled flow from the tip.
5. Before applying, dispense a small sample of etchant from tip onto a mixing pad to ensure evenness and to become familiarized with flow rate. If there is excess resistance to flow, DO NOT proceed. Attach a new tip and test again before using on patient. Dispose of removed tip immediately (according to government regulations) to avoid contact.
6. Express an even coating of Porcelain Etch onto prepared porcelain (Fig.2) using the Inspirial Brush tip. Etch porcelain 90 seconds. (note Fig.3 and 4 showing before and after SEMs)
7. Assistant should hold vacuum tip adjacent to the surface while the dentist dispenses the Porcelain Etch. This ensures removal of any irritating vapors while acid reacts on porcelain (90 seconds). To neutralize the Porcelain Etch, blend EtchArrest into the etchant until the amber color of the etch is no longer identifiable.
8. Remove neutralized acid by placing the vacuum tip next to the surface and then rinsing with water spray. Rinse thoroughly and dry. Porcelain should have a frosted appearance. Repeat etching if not.
9. Apply Ultra-Etch for 5 seconds to remove porcelain salts and debris formed by hydrofluoric etchant. Rinse and dry.
10. Apply Silane with a Mini Brush tip. Let evaporate for 60 seconds. If not completely dry after 60 seconds, air dry with oil-free air.
11. Place bonding resin according to product instructions.

**Important Note:** Testing shows highest bonding values when etched porcelain is silanated with Ultradent Silane followed by Peak Universal Bond bonding agent in the following manner: Apply Silane to porcelain using Mini Brush tip. Gently brush the Silane into the porcelain for 60 seconds using small strokes. Air dry and proceed with application of Universal Bond.

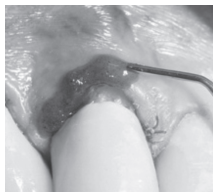


Fig. 1 Protective bead of EtchArrest is placed on soft tissues adjacent to the tooth surfaces.



Fig. 2 Carefully express an even coating of Ultradent Porcelain Etch to prepared porcelain.

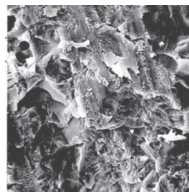


Fig. 3 SEM of diamond-ground porcelain.

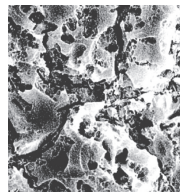


Fig. 4 Note increased surface area and undercuts afforded by etch with Porcelain Etch for 90 seconds.

**Precautions:**

1. Caution: Chemical may set in tip after a few hours. To avoid clogging, remove tip and re-cap with Luer Lock Caps between each use. Always verify material flow prior to applying intraorally. If resistance is met, replace tip and re-check. This does NOT apply to dual-barrel syringes and mixing tips.
2. Operator, assistant, and patient must wear protective eyewear.
3. Replace luer lock caps on syringes when not in use. Tips are disposable.
4. We recommend Ultradent Syringe Covers for a protective barrier to prevent cross-contamination.
5. Clinician and patient must wear protective eyewear with side shields when handling or applying this product.

**General Precautions:**

1. Review instructions, precautions, and SDS before beginning treatment. Use only as directed..
2. For Professional use only.
3. Keep products out of heat/sunlight.
4. Avoid skin exposure to resins.
5. Isolate strong chemicals to area of treatment.
6. Test flow of materials from syringe and tip before using intraorally.
7. Never force syringe plungers.

Please visit [www.ultradent.com](http://www.ultradent.com) for product technical instruction.

Ultradent syringes have an expiration date stamped on the side of the syringe consisting of one letter and three numbers. The letter is a lot number used for manufacturing purposes and the three numbers are the expiration date. The first two numbers are the month, and the third number is the last number of the year.

**Transport and Storage condition:**

Store in room temperature.

**Manufacturing date / expired date:**

Find it in the product label

**Explanation for the symbols in the product label:**



See instructions



Do not re-use to avoid cross contamination.



Catalog number



Use by date



Lot number



Manufacturer



For professional use only



Recycle

**Revision date:**

June, 2020

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Contact: 020-84156506

Registration number/ Product technical requirement Number: 国械注进20162632247

Product Name: Porcelain Etch and Silane  
Model: 405, 406, 410 (details see below table)

Model	Description	Configuration
406	Porcelain Etch Syringe 2pk	2x1.2mL
405	Porcelain Etch kit	2x1.2mL (Porcelain Etch)
		2x1.2mL (Saline)
		20 x Black Mini Brush tips 20 x Inspirial Brush tips
410	Silane Syringe 2pk	2x1.2mL

**Porcelain Etch & Silane**

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



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