Instructions For Use

urolon™

aqlane™ MEDICAL

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0344


Attention: see instructions for use


Electronic instructions for use: **www.urolon.com/ifu**

Syringe contains a sterile fluid path that is sterile by aseptic processing
Syringe exterior is non sterile


Do not use if package is damaged


Do not re-use

Storage temperature limits

Ref

Batch No.


Use by

DESCRIPTION

Urolon™ is a non-pyrogenic, totally bioresorbable, non-permanent implant, whose principle component is synthetic polycaprolactone (PCL) microspheres suspended in a gel carrier of phosphate buffered saline (PBS), glycerin and carboxymethylcellulose (CMC). PCL is a well-known totally bioresorbable soft medical polymer. PCL is used in numerous CE-marked and Food and Drug Administration (FDA) approved commercial bioresorbable product applications for several decades world-wide and has demonstrated an excellent safety profile.

MODE OF ACTION

Urolon™ is injected sub-mucosally between the bladder neck and mid-urethra. The injection of Urolon™ creates increased tissue bulk and soft tissue augmentation of the urethra. The gel carrier suspends the PCL particles and allows delivery through injection needles and is dissipated *in vivo*, while the PCL particles remain at the injection sites and provide the tissue bulking to increase urethral resistance to urine leakage.

INDICATIONS FOR USE

Urolon™ is indicated for soft tissue augmentation in the treatment of stress urinary incontinence (SUI) in adult females.

CONTRAINDICATIONS

- In patients with significant history of urinary tract infections without resolution.
- In patients with current or acute conditions of cystitis or urethritis.
- In patients with fragile urethral mucosal lining.
- In patients with uncontrolled detrusor overactivity.
- In patients with high grade pelvic organ prolapse.
- In patients with confounding bladder pathology.
- In patients with morbid obesity.
- In patients with vulvar vestibulitis.
- In patients that had any previous permanent bulking agent treatment.

WARNINGS

- Only the syringe content is sterile. The exterior of the syringe is non sterile. Prevent cross-contamination.
- Overcorrection using Urolon™ may lead to obstruction or urinary retention.
- Avoid injecting Urolon™ in blood vessels. Urolon™ injection into blood vessels may cause vascular occlusion.
- Avoid using Urolon™ in patients with non-viable tissue, e.g., history of significant pelvic irradiation, multiple pelvic surgeries, etc. Scar tissue and significantly compromised tissue will not coapt appropriately.
- Urolon™ should not be used in patients with urethral or bladder neck strictures until the strictures have been corrected. Use of Urolon™ in patients with strictures may cause injury and/or urethral obstruction.
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- The safety and effectiveness of Urolon™ treatment during pregnancy has not been established.
- As with any implant material possible adverse reactions that may occur include, but are not limited to: hypersensitivity, allergic reactions, inflammation, erythema, embolic phenomena, vascular occlusion, worsening of incontinence, urinary urgency, hypertonic bladder, urinary retention, urethral disorder, back pain, bladder spasm, dysuria, injection site reaction, mucosal erosion, nodule or granuloma formation, peripheral edema, urinary tract obstruction, hematuria, inflamed introitus, anterior bladder neck swelling, urinary tract infection, urge incontinence and burning on urination.
- Adverse events, other than mentioned above, could occur as with any medical intervention.
- If corrective surgery is required to remove the device this may lead to urethral obstruction.
- Women with peripheral vascular disease and prior pelvic surgery may be at increased risk for tissue erosion following injection of Urolon™.

PRECAUTIONS

- As with similar urologic procedures, the treatment and instrumentation associated with the injection of Urolon™ carry a risk of infection and/or bleeding. The usual precautions associated with urologic procedures, specifically cystoscopy, should be followed.
- It is recommended to administer prophylactic broad-spectrum antibiotics.
- Safety and effectiveness of Urolon™ in patients with any form of previous SUI surgery has not been established.
- Safety and effectiveness of periurethral injection of Urolon™ has not been established.
- Safety and effectiveness of Urolon™ in men has not been established.
- Safety and effectiveness of Urolon™ in patients with a previous bulking agent treatment has not been established.
- Safety and effectiveness of Urolon™ in patients with a history of (pelvic) radiation treatment or currently undergoing (pelvic) radiation treatment has not been established.
- The effect of Urolon™ on subsequent pregnancy and delivery, and the impact of subsequent pregnancy on the effect of Urolon™, is unknown. Therefore, the risks and benefits of the device in women of childbearing potential should be carefully assessed.
- Do not re-sterilize.
- Do not use if the foil pouch is compromised or the syringe has been damaged.

- Do not use if the syringe end cap or syringe plunger are not in place or removed.
- Dysuria, hematuria, and frequency of micturition are to be expected post-treatment. If any of these conditions persist past 48 hours, the patient should be instructed to contact the treating physician immediately.
- Post-treatment retention may occur which may necessitate intermittent catheterization. If the patient remains unable to void freely, continued intermittent catheterization may be necessary.

PHYSICIAN TRAINING

To use Urolon™, physicians must have training in diagnostic and therapeutic cystoscopy. This device should only be used by practitioners trained in the field of urinary incontinence and bulking agents.

PATIENT COUNSELING

AQLANE Medical™ relies on the physician to advise the patient of all potential risks and benefits associated with a Urolon™ implant procedure. Patients should be fully apprised of the indications, contraindications, warnings, precautions, expected clinical outcomes, adverse events, and methods of implantation. Patients should be advised that bulking agent therapy with Urolon™ is positioned as a single treatment procedure, however, more than one injection procedure may be required to achieve dryness or a desired level of improvement in incontinence. Patients should be counseled to report adverse events to the treating physician. Physicians are advised to report adverse events to AQLANE Medical™.

DIRECTIONS FOR USE

The following is recommended for a transurethral injection of Urolon™:

- 35 cm cystoscopic injection needle with a 23 gauge needle tip.
- A compatible cystoscope.

1. Using standard procedure, prepare the patient for cystoscopy.
2. It is recommended to administer prophylactic broad-spectrum antibiotics before treatment.
3. Prepare the syringes of Urolon™, injection needle(s), and cystoscopic equipment before injection. Be aware that the exterior of the syringe is non-sterile; prevent cross-contamination. A new injection needle may be used for each syringe or the same injection needle may be connected to each new syringe. Prepare cystoscopic equipment according to the manufacturer's instructions for use.
4. The urethra and bladder neck should be examined prior to injection.
5. Remove the Luer syringe cap prior to attaching the injection needle. The syringe of Urolon™ can then be twisted onto the Luer lock fitting of the injection needle. The injection needle must be tightened securely to the syringe. Prime the injection needle by slowly pushing the syringe plunger until Urolon™ extrudes from the injection needle.
6. The injection needle is then advanced through the working channel of the cystoscope. A desired location for the injection into the urethra needs to be identified. This is usually 1 to 1.5 cm distal to the bladder neck. Push the injection needle into the sub-mucosal lining of the urethra at the desired site. Slowly push the plunger shaft of the Urolon™ syringe to start the injection.
7. When Urolon™ starts to flow into the injection site tissue bulking in the form of a bleb should be visible. If it is not observable, pull back on the injection needle and locate the needle more superficially and begin injecting again. This site should be injected until the bleb meets the midline of the urethra or maximum tissue compliance. Additional sites should be injected until the urethral opening shows optimal coaptation.
8. Multiple syringes may be required to achieve optimal coaptation. The injection needle already in place may be used with each new syringe of Urolon™ or a new injection needle may be used. If a new injection needle is used, the needle must be secured to the syringe. Prime the needle with Urolon™ prior to insertion into the cystoscope. If a new syringe is used (with the same needle) ensure the syringe is primed before connecting it to the needle.
9. After the injections have been completed, it is important not to pass the cystoscope through the coaptation site as this may deform the tissue blebs that have been formed.
10. Prior to discharge patients must be able to void freely. In case of urinary retention, intermittent catheterization (12 Fr or smaller) may be required until normal voiding resumes.
11. Used syringes and used injection needles represent biohazardous waste and should be disposed of in accordance with facility medical practices and applicable regulations.

HOW SUPPLIED

Urolon™ is a non-pyrogenic bulking agent, supplied in single use, 1 ml syringes. The syringe is packaged in a foil pouch. The Urolon™ product box contains 3 pouches.
Upon receipt of shipment, check the packaging to ensure that the packaging is intact and there has been no damage from shipment. The contents of the syringe are intended for single patient use only and cannot be re-sterilized.

SHELF LIFE AND STORAGE

Urolon™ should be stored at a controlled room temperature (15°C - 25°C: 59F - 77F). The expiration date, when stored in these temperatures, is two years from date of manufacture. Do not use if the expiration date has been exceeded. Do not use if package is opened or damaged.

WARRANTY

AQLANE Medical™ warrants that reasonable care has been exercised in the design and manufacture of this product.
THIS WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES NOT EXPRESSLY SET FORTH HEREIN, WHETHER EXPRESSED OR IMPLIED BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ITS PARTICULAR PURPOSE.
Handling and storage of this product, as well as factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond AQLANE Medical™'s control directly affect the product and the results obtained from its use. AQLANE Medical™'s obligation under this warranty is limited to the replacement of this product and AQLANE Medical™ shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly, arising from the use of this product. AQLANE Medical™ neither assumes, nor authorizes any person to assume for AQLANE Medical™, any other or additional liability or responsibility in connection with this product.


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注意：
請參閱使用說明


使用說明書(網路版)：
www.urolon.com/ifu

注射針筒包含無菌液體的路徑，
皆已經過滅菌處理
注射針筒的外部並非無菌狀態


包裝如有損壞，
請勿使用


請勿重複
使用

儲存溫度
限制

參考

批號


使用者

產品說明

Urolon™是無熱原因子、生物可完全吸收的非永久性植入物。其主要成份是聚己內酯(PCL)製成的微型晶球，懸浮於一種由磷酸鹽緩衝鹽水（PBS）、甘油和羧甲基纖維素（CMC）所組成的凝膠載體。 PCL是眾所皆知生物可完全吸收、柔軟的醫用聚合物。 數十年來，PCL已被廣泛運用在各種可被人體吸收的醫療產品上，且經歐盟(CE mark)及美國食品藥物管理局(FDA)所許可，廣泛應用於全球，並顯示極佳的安全資料。

作用方式

Urolon™是在膀胱頸或中間尿道的子粘膜層(sub-mucosally)內進行注射。注射Urolon™後，會將膀胱頸和尿道的軟組織體積增加，並使其增大。PCL顆粒懸浮於凝膠載體，可經由通過注射到體內並在體內降解，PCL顆粒保留在注射部位，提供組織填充以使尿道括約肌接合並增加尿道阻力，減少漏尿。

適應症

Urolon™ 適用於治療成年女性應力性尿失禁 (SUI) 的軟組織增大療程。

使用禁忌

- 患者有明顯的尿路感染史但未得到解決
- 目前處於急性膀胱炎或尿道炎的患者
- 尿道粘膜層脆弱的患者
- 逼尿肌過度活動(膀胱過動症)，且無法控制的患者
- 骨盆腔器官高度脫垂的患者
- 罹患混淆性膀胱病變的患者
- 病態肥胖患者
- 外陰前庭炎(vulvar vestibulitis)患者
- 先前有使用過任何永久性填充劑治療的患者

警告事項

- 只有注射針筒的內容物是無菌的。注射針筒的外部爲非滅菌狀態。避免交叉污染。
- 過度使用 Urolon™ 矯正可能導致阻塞或尿滯留。
- 避免將Urolon™注射至血管內。Urolon™注射至血管可能導致血管閉塞。
- 避免在患者的無活力組織使用 Urolon™，例如：有顯著的骨盆腔照射記錄、多次骨盆腔手術等。疤痕組織和顯著受損的組織將不會得到適當的組織接合 。
- 患者尿道或膀胱頸狹窄，不應使用Urolon™，除非狹窄已被糾正。在上述症狀的患者使用 Urolon™ 可能會導致尿道受傷和/或阻塞。
- 在懷孕期間使用 Urolon™ 治療的安全性和有效性尚未確立。
- 與任何其他植入物一樣，可能出現的不良反應包括(但不僅限於以下反應)：
  高敏感性、過敏反應、發炎、紅斑、栓塞現象、血管閉塞、尿失禁惡化、尿急、高張性膀胱、尿滯留、尿道病症、背部疼痛、膀胱痙攣、排尿困難、注射部位反應、粘膜糜爛、結節或肉芽腫的形成、周邊水腫、尿道阻塞、血尿、陰道口紅腫、前膀胱頸部水腫、尿道感染、急迫性尿失禁和排尿灼熱感。
- 除了上述情況外，不良事件也可能發生在任何侵入性醫療行爲。
- 如果進行矯正手術移除植入物是必須的，將可能會導致尿道阻塞。
- 女性患者若有周邊血管疾病與骨盆腔手術病史，注射Urolon™後可能促使組織侵蝕(Tissue erosion)的風險增加。

注意事項

- 與類似的泌尿外科手術程序一樣，注射 Urolon™ 時使用的相關治療和儀器都存在感染及/或出血的風險。應遵循與泌尿外科手術有關的一般預防措施，特別是膀胱鏡檢查。
- 建議施用預防性廣效型抗生素。
- 曾以任何形式對應力性尿失禁(SUI)進行手術的患者，在使用Urolon™的安全性和有效性尚未確立。
- 注射 Urolon™ 時，尿道周圍的安全性和有效性尚未確立。
- Urolon™ 在男性使用的安全性和有效性尚未確立。
- 曾使用其他填充劑治療的患者，在使用Urolon™的安全性和有效性尚未確立。
- Urolon™ 對有（骨盆腔）放射治療記錄，或目前正在接受（骨盆腔）放射治療的患者，在使用上的安全性和有效性尚未確立。

- Urolon™對後續的妊娠和分娩，以及隨後的妊娠對效果的影響是未知的。因此，婦女應仔細評估潛在的風險和益處。
- 請勿重新消毒。
- 如果鋁箔袋包裝破損或注射針筒已損壞，請勿使用。
- 如果注射針筒前蓋或注射針筒的封口掉落或移位， 請勿使用 。
- 術後可被預期的症狀爲：排尿困難，血尿和頻尿。如果這些狀況持續48小時以上，患者應立即聯繫主治醫師。
- 術後可能需要間歇性導尿的暫留措施。如果病人仍然無法自主排尿，持續間歇性導尿可能是必要的。

醫師培訓

醫師必須具有膀胱鏡檢查和治療的專業訓練後才能使用Urolon™。該產品只能由受過尿失禁專業訓練和使用膨脹劑的相關領域執業人員所使用。

患者諮詢

醫師需告知病患 Urolon™植入手術療程，所有相關潛在的風險和益處。患者應充分了解其適應症、使用禁忌、警告事項、預防措施、預期臨床療效、不良事件和植入的方法。患者應注意，Urolon™填充劑雖爲一次性的療程，但爲達到尿失禁患者期望改善症狀之水準，必需視情況，可能有超過單次以上的注射療程。若有不良事件，請患者通知主治醫師，亦請醫師通知AQLANE Medical™。

使用方式

以下爲經尿道注射 Urolon™時的建議：

- 35 釐米膀胱鏡注射針頭搭配23 號針尖。
- 相容的膀胱鏡。

1. 使用標準程序，準備對患者進行膀胱鏡檢查。
2. 建議在治療前先執行預防措施，使用廣效性抗生素。
3. 注射前，請先準備好裝有Urolon™ 的注射針筒、注射針頭和膀胱鏡設備。請注意，注射針筒的外部未經過滅菌; 請避免交叉污染。請確認全新的注射針頭已連接至新的注射針筒。依據膀胱鏡製造商使用說明準備膀胱鏡設備。
4. 注射前，請先檢查尿道和膀胱頸。
5. 在連接注射針頭前，請先取下Luer氏針筒的前蓋。然後，將注射針頭拴緊在Urolon™注射針筒的Luer氏鎖緊裝置上。注射針頭必須與注射針筒牢固的拴緊。緩慢地推送針筒推桿，直到Urolon™從針頭尖端擠出。
6. 將注射針頭推進通過膀胱鏡的工作通道。需要進行標識尿道或膀胱頸期望注入的位置。距離通常是膀胱頸前方1至1.5厘米。推送針頭進入所需部位尿道的子粘膜內層。慢慢推送Urolon™注射針筒的推桿，開始進行注射。
7. 當Urolon™ 流入注射部位時，被注射部位組織應會以填充形式膨脹，此現象應是可見的。如果無法觀察到此現象，請將注射針頭拉回並到較表淺處定位針頭後，再次開始注射，直到滿足尿道或此組織容許的最大中線即停止。其他部位應注射至尿道開口顯示最佳接合爲止。
8. 可能需要同時使用數隻針劑，才能實現尿道括約肌的最佳接合。準備好的注射針頭可以搭配每個新的Urolon™ 注射針筒使用，也可以使用全新的注射針頭。若使用新的注射針頭，必須確認針頭已牢固的拴緊在針筒上。插入膀胱鏡前，請使用有 Urolon™ 的注射針頭。如果使用新的注射針筒（相同的針頭），請確認注射針筒在連接到針頭前已準備好。
9. 注射完成後，請勿讓膀胱鏡通過尿道括約肌的接合點，避免破壞已形成的膨大組織。
10. 出院前，患者必須能夠自由排尿。如果有尿滯留的現象，可能需要間歇導尿（12 Fr 或更小），直到恢復正常排尿。
11. 使用過的注射針筒和注射針頭可能會有生物危險，其應依照我國醫療器材相關的醫療器材拋棄法規定標準來管制和處理。

包裝方式

Urolon™是無熱原因子的填充劑，1隻針筒內含1ml的Urolon™，僅供單次療程使用。每盒Urolon™產品內含3個鋁箔袋，每個鋁箔袋內含一隻裝有Urolon™的注射針筒。

收到產品後，請先檢查包裝，確認包裝完好無損，並沒有在運輸過程中受到任何損壞。此產品僅供患者單次使用，不得重新消毒。

效期和儲藏方式

Urolon™應存放在攝氏15℃ - 25℃/華氏59F - 77F之間的環境內。儲存在上述溫度下的產品有效期爲自生產日後算起的兩年。若產品有效期限已過、產品包裝已被開啓或損壞，則不可使用。

保證

AQLANE Medical™保證本產品的設計和製造過程皆依照相關的規範進行之。

此擔保取代並排除本協議未明確規定的所有其他擔保，無論是由法律或其他方式明示/暗示，包括但不限於對適銷性或適用於其特定用途的任何暗示擔保。

本產品的處理、儲存，以及有關患者、診斷、治療、手術療程和AQLANE Medical™控制範圍以外的其他相關因素將直接影響產品及其使用後所獲得的結果。

AQLANE Medical™依據此保證的義務僅限於產品的更換，AQLANE Medical™不對使用產品而直接/間接造成的任何意外或隨之發生的損失，承擔相關責任及費用。AQLANE Medical™亦不授權任何第三方爲AQLANE Medical™承擔與本產品有關的任何其他或額外的義務/相關責任。

For more information please visit

www.urolon.com

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