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**Transurethral Balloon Catheter**  
Instructions for use

(ZH)

**经尿道球囊导管**  
使用说明

(JA)

**経尿道バルーンカテーテル**  
使用説明書

(RU)

**Трансуретральный  
баллонный катетер**  
Руководство по эксплуатации

(AR)

القسطرة البولية  
عن طريق الإحليل  
سلة الحصىات

(TR)

**Transürettral Balon Kateter**  
Kullanma talimatları

## GANL Nr. 15-D

(ZH)

**使用说明**

**经尿道球囊导管**

GANL Nr. 15-D\_ZH /7/10.09.2019

***请注意：***本医疗产品仅允许由经过培训的护士和医务人员获取和使用。如将本产品用于非预期用途，会造成严重且不可逆转的伤害。

#### 1.描述

双腔经尿道球囊导管采用医疗级硅胶或乳胶制成，带硅胶涂层。

#### 2.内容和包装

- 双腔标准 Nelaton 和 Tiemann 尖端  
- 双腔 Nelaton 尖端，带集成球囊  
- 双腔 Nelaton 尖端，超软  
- 双腔乳胶带硅胶涂层, Nelaton 尖端  
- 双腔笛口样导管  
- 导管塞和加强导引针（如有需要）  
- 双层包装及使用说明

#### 3.预期用途

长期（重复）用于经尿道膀胱排尿。

#### 4.适应症

- 下尿路诊断  
- 膀胱排空障碍  
- 用于经尿道膀胱导管术

#### 5.禁忌症

- 急性前列腺炎  
- 疑似尿道损伤  
- 对导管材料的已知过敏反应

#### 6.可能的副作用

- 尿道黏膜的压迫性溃疡或炎症  
- 感染（细菌尿）  
- 导管结垢和阻塞  
- 尿道损伤  
- 血尿

#### 7.说明

使用本产品时，必须遵守适用于导尿操作的一般卫生规则。

#### 插入技术（男性）

根据医疗标准针对各个患者选择球囊导管的尺寸。

使用一次性注射器向尿道口注入常规医疗润滑剂。然后手动扩张外尿道口，置于针推，推入注射头，缓慢注入润滑剂。要确保润滑剂不会泄漏，应暂时按住尿道或使用阴茎夹夹住。

使用左手，将阴茎保持在阴茎头侧边。然后使用无菌护套或无菌镊子插入导管。用小手指和无名指夹住其开放端，以此方式固定。如果导管的尖端是弯曲的，尖端必须向上指。将导管平稳推过括约肌，并不断检查，直到其位于膀胱中并能引出尿液。

然后使用活瓣以及注射器鲁尔附件，将导管再向前推几厘米，封锁第二个腔，再将导管往后拉，以便调整其在膀胱中的位置。一旦插入导管后，它通过活瓣连接到尿路造口袋上的单向连接，然后牢牢按在上面。

#### 插入技术（女性）

同样根据医疗标准选择适合女性的球囊导管尺寸。

一侧使用一根棉签，从耻骨到肛门对大阴唇消毒，然后使用拇指和食指展开。以同样的方式对小阴唇消毒。

在整个管术过程中，一只手展开阴唇，只用另一只手执行导管插入。一旦注入润滑剂后，将导管引入尿道口，缓慢向前推进，直到它到达膀胱并引出尿液。

然后使用活瓣以及注射器鲁尔附件，将导管再向前推几厘米，封锁第二个腔，再将导管往后拉，以便调整其在膀胱中的位置。一旦插入导管后，它通过活瓣连接到尿路造口袋上的单向连接，然后牢牢按在上面。

**取出导管**  
取出前必须完全排空球囊。为此，在活瓣上放置一个空的注射器，抽吸液体，直到形成真空。然后可以小心取出导管。

#### 8.可能出现的并发症和/或风险

- 导管长时间插入可能会导致膀胱收缩。  
- 感染  
- 积垢  
- 导管错位  
- 推进导管时缺乏适当的护理可能损伤膀胱壁。  
- 膀胱结石可能会破坏球囊。

#### 9.使用说明/注意事项

- 此产品仅在包装未损坏和未开封条件下才为无菌状态。  
- 只可使用一次！勿重复使用、回收或重新消毒。重复使用、回收或再消毒可能会损害仪器的结构完整性和/或导致仪器发生故障，从而导致患者发生疾病、伤害或死亡。  
- 请勿使用已过有效期的导管。  
- 请勿使用酒精/消毒剂/润滑剂擦拭产品。这可能会损坏表面。  
- 所有组件都必须在使用前仔细检查。不可使用可能已损坏的产品。  
- 请勿过度堵塞球囊！仅堵塞至指定的最大容积。（参见导管附件和/或标签了解详情说明）  
- 定期检查导管引流系统的有效性和位置。应间隔 1-2 周检查球囊的加注量。如有需要，应考虑更换导管。  
- 为减少尿路感染，导管和尿路造口袋之间的连接最好不要断开。建议使用闭合排尿系统。  
- 要重新充填球囊，先将其完全排空。低压充填球囊。为减少球囊中的容积损失风险，应使用蒸馏水+10% 甘油。  
- 全硅胶导管、涂有 Visioslide 层的硅胶导管以及带硅胶弹性体涂层的导管必须在 30 天内更换。  
- 特殊情况下，可能无法开启该球囊。在这种情况下，可以采取各种措施来排空球囊（如切开活瓣、通过耻骨上切口穿刺球囊等）。使用者必须根据个别情况决定采用最适当的措施。  
- 请勿夹住导管，如有需要请使用密封胶。  
- 对于带加强导引针的导管，在插入导引针前应在球囊导管上涂抹润滑剂，以便取出导引针。  
- 使用含乳胶的导管前，请确认患者不会对乳胶过敏。

#### 10.与其他药物的相互作用

导管在与不同药物同时使用，甚或与尿液接触后可能出现褪色现象。

#### 11.运输和储存条件

只能使用专用包装运输和储存产品。没有进一步的具体运输要求。

产品必须储存在干燥处，避免阳光直射，储存温度范围为 5 - 30 摄氏度。

#### 12.处理方式

使用后，该产品可能会造成生物危害。产品的处理和处置操作必须按照认可的医疗程序进行，并遵守适用的法律法规和指导方针完成。

(EN)

**Instructions for use**

**Transurethral Balloon Catheter**

GANL Nr. 15-D\_EN /7/10.09.2019

***Please note:*** This medical product may only be obtained and used by trained nursing and medical personnel. Non-intended use of the product can cause serious and irreversible damage.

#### 1. Description

Two-lumen transurethral balloon catheters made from medical grade silicone or latex with silicone elastomer coating.

#### 2. Contents and packaging

- 2-way standard, Nelaton and Tiemann tip  
- 2-way Nelaton tip with integrated balloon  
- 2-way Nelaton tip, supersoft  
- 2-way latex with silicone elastomer coating, Nelaton tip  
- 2-way whistle tip catheter  
- Catheter plug and, if necessary, stiffening mandrin  
- Double packaging and instructions for use

#### 3. Intended use

Longterm (repeated) transurethral use for draining urine from the bladder.

#### 4. Indication

- Diagnostics of the lower urinary tract  
- Bladder emptying disorders  
- For transurethral bladder catheterization

#### 5. Contraindications

- Acute prostatitis  
- Suspected urethral trauma  
- Known allergy to the catheter material

#### 6. Possible side effects

- Pressure ulceration or inflammation of the urethral mucosa  
- Infections (bacteriuria)  
- Catheter incrustation and obstruction  
- Urethral injury  
- Hematuria

#### 7. Instructions

When using this product, the general hygiene rules applicable to catheterization must be complied with  
**Insertion technique (men)**

The size of the balloon catheter is selected on an individual patient basis in accordance with medical standards. Conventional medical lubricant is drizzled onto the urethral opening using a disposable syringe. The outer urethral meatus is then widened manually, the cone positioned and the lubricant instilled by extending the head. To ensure that the lubricant does not leak out, the urethra should be held compressed for a moment or closed off with a penis clamp.

With the left hand, the penis is then held lateral to the glans penis. The catheter is then inserted with the sterile sheathing or sterile forceps. Its free end is grasped between the pinkie and ring finger and secured in this way. On catheters with curved tips, the tip must point upwards. The catheter is then advanced smoothly past the sphincter with constant checks until it is inside the bladder and urine is draining out. The catheter is then advanced by a few cm and, using the valve and the Luer attachment on a syringe, blocked through the second lumen and adjusted in the bladder by pulling it backwards. Once the catheter has been inserted, it is connected via the valve to a one-way connection on a urine bag and firmly pressed.

The catheter is then advanced by a few cm and, using the valve and the Luer attachment on a syringe, blocked through the second lumen and adjusted in the bladder by pulling it backwards. Once the catheter has been inserted, it is connected via the valve to a one-way connection on a urine bag and firmly pressed.

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(JA)

**使用方法**

**経尿道バルーンカテーテル**

GANL Nr. 15-D\_JA /7/10.09.2019

***ご注意：***この医療製品は、訓練を受けた介護・医療従事者のみにより入手、ご使用いただけます。製品の意図しない使用は、重大かつ不可逆的な損傷を引き起こす可能性があります。

#### 1.概要

2 ルーメンの医療グレードのシリコンまたはラテックス製経尿道バルーンカテーテルで、シリコンエラストマーコーティングが施されています。

#### 2.内容と包装

- 2方向標準NelatonおよびTiemann先端  
- 2方向Nelaton先端、統合バルーン付き  
- 2方向Nelaton先端、スーパーソフト  
- 2方向ラテックス、シリコンエラストマーコーティング、Nelaton先端  
- 2方向ホイッスルチップカテーテル  
- カテーテルプラグおよび必要であれば硬直マンドリン  
- 二重包装と使用方法

#### 3.使用目的

膀胱から尿を排出するための長期（反復）的経尿道使用。

#### 4.適応症

- 下部尿路の診断  
- 排尿障害  
- 経尿道膀胱カテーテル法

#### 5.禁忌

- 急性前立腺炎  
- 尿道外傷の疑い  
- カテーテル素材に既知のアレルギーがある場合

#### 6.起こり得る副作用

- 褥瘡形成または尿道粘膜の炎症  
- 感染症（細菌尿症）  
- カテーテル痂皮形成および閉塞  
- 尿管損傷  
- 血尿

#### 7.説明

この製品の使用時には、カテーテルに適用される一般的衛生規則に遵守しなければなりません。  
**挿入テクニック（男性）**  
医療標準に基づき患者ごとにバルーンカテーテルのサイズを選択します。

使い捨ての注射針を使用して、通常の医療用潤滑剤を尿管開口部に塗布します。その後、尿道口を手で広げ、ヘッドを伸ばしてコーンを配置し、潤滑剤を注入します。潤滑剤が漏れないようにするため、尿道を短時間、圧迫するか、ペニス・クランプで閉じます。その後、亀頭が横になるように陰茎を左手で保持します。滅菌被覆材または滅菌鉗子を使ってカテーテルを挿入します。もう片方の端は小指と薬指の間にはさんで、示されているように固定します。先端の曲がったカテーテルでは、先端は上向きになっていないではありません。その後、常にチェックしながら括約筋を超えて膀胱内部までカテーテルをスムーズに進め、尿を排出します。カテーテルをさらに数 cm 進め、バルブと注射器のルーア 付属品を使い、2 番目のルーメンを通してブロックし、少し引き戻して膀胱内で調整します。カテーテルは挿入後、バルブを介して尿バッグに一方方向で接続し、しっかりと押さええます。

The catheter is then advanced by a few cm and, using the valve and the Luer attachment on a syringe, blocked through the second lumen and adjusted in the bladder by pulling it backwards.

Once the catheter has been inserted, it is connected via the valve to a one-way connection on a urine bag and firmly pressed.

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#### Removal of the catheter

The balloon must be completely drained before removal. To do this, place an empty syringe on the valve and aspirate the fluid until a vacuum forms. The catheter is then carefully removed.

#### 8. Possible complications and/or risks

- Long-term catheterization can cause shrinkage of the bladder.  
- Infections  
- Incrustation  
- Catheter dislocation  
- Lack of proper care when advancing the catheter may damage the bladder wall.  
- Bladder stones can damage the balloon.

#### 9. Instructions for use / Precautions

- This product is only sterile if the packaging is undamaged and unopened.  
- For single use only! Do not re-use, recycle, or re-sterilize. Re-using, recycling, or re-sterilizing can impair the structural integrity of the instrument and/or lead to malfunctioning of the instrument, which can in turn lead to illness, injury, or death of the patient.  
- Do not use catheter after the date of expiry has passed  
- Do not treat the product with alcohol/disinfectant agents/lubricants. This may damage the surface.  
- All components must be carefully checked before use. Products that may be damaged must not be used.  
- Do not over-block the balloon! Only block to the maximum volume specified! (Details can be found on the catheter attachment and/or on the label)  
- Check the catheter regularly for drainage effectiveness and position. The fill volume of the balloon should be checked at intervals of 1-2 weeks. If necessary, catheter replacement should be considered.  
- To reduce the risk of urinary tract infections, the connection between the catheter and the urine bag should ideally not be released. Closed drainage systems are recommended.  
- To refill the balloon, drain it completely first. Fill the balloon with slight pressure. To reduce the risk of loss of volume in the balloon, distilled water/+10% glycerin should be used.  
- Fully silicone catheters, silicone catheters with a Visioslide coating and silicone elastomer-coated catheters must be changed after no more than 30 days.  
- In exceptional cases, it may be impossible to unblock the balloon. In this situation, various measures can be used to drain the balloon (e.g. cutting the valve, puncturing the balloon with a suprapubic incision, etc.). The user must decide on the most appropriate measure based on the individual situation.  
- Do not clamp the catheter; use a sealing plug if necessary.  
- For catheters with stiffening mandrins, lubricant shall be applied to the balloon catheter before the mandrin is inserted in order to make removal of the mandrin easier.  
- Check that the patient does not have an allergy to latex before using catheters that contain latex.

#### 10. Interaction with other drugs

The catheter could potentially discolor due to the concomitant administration of medication or even as a result of contact with urine.

#### 11. Transport and storage conditions

The products may be transported and stored only in the packaging intended for this. There are no further specific requirements for transport. Products must be stored dry and protected from direct sunlight, in the temperature range of 5 - 30 degrees Celsius.

#### 12. Disposal

After use, this product may pose a biological hazard. Handling and disposal must be carried out in accordance with recognized medical procedures and be completed pursuant to applicable legal regulations and guidelines.

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