

Instruction for Use

Nottingham Dilators

Device Description

Nottingham Dilator is used in Urology Procedures for the one step dilation of Intramural tunnel and ureter. Supplied sterile in peel-open pouch. Intended for single use. Duration of Contact with the body is 1 day. The configurations available include:

Family	Size (Fr.)	Length (cm)	Catalogue Number	Colors
Nottingham Dilator (ND)	10/5	30	AMPLDL005	Grey
	10/6	70		
	12/6			
	12/7			
	14/7			
	16/6			
	16/7			
	18/7			

Intended Purpose

Nottingham Dilators are used to dilate the intramural tunnel and ureter in one step. They can also be used to inject contrast medium to determine sub mucosal tunneling or anesthetic jelly to aid in dislodging ureteral stones.

Performance Characteristics of the Device

Nottingham Dilator aids in the dilation of intramural tunnel and ureter. The smooth surface of the dilator helps in ease of introduction of the device. Provided with Long and Uniform Tapering to reduce trauma. Radiopaque for better visualization.

Indications

- One Step dilation of the intramural portion and ureter
- May also be used to inject female luer adapter at proximal end

Contraindications

- Active Urinary Tract Infection
- Uncorrected Bleeding Diathesis
- Un cooperative Patient

Precautions & Warnings

Carefully read all instructions for use and product labeling. The device shall only be applied for its intended use and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

Precautions:

- All medical staff is responsible for using the appropriate technique and deciding on the indication for use of this device based on own experience, training and medical judgment. The doctor must be trained in the proper use of the device.
- The Intended User of the device must be a Urologist specializing in the treatment of urinary system disorders and related urological procedures.
- Do not use the device if there is any indication that the sterility of the device has been compromised.

Warnings:

- All components of the Nottingham Dilators are for single use only.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient: Bio-contamination due to release of infectious agents from device into the body which further may result in Urinary Infection.
- This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

Intended Patient Population

- Nottingham Dilator is used in patients diagnosed with Ureteral Strictures (due to vicious cycle of ischemia and scarring, by external trauma or may develop after treatment for another condition) and Hydronephrosis.
- To treat Ureteral stones.
- The above-mentioned sizes are used in the treatment of patients above the age of 18yrs having the above-mentioned conditions.
- The above -mentioned sizes are not recommended for use in infants and patients below the age of 18yrs.

Shelf-life and storage condition of the Product

- The shelf life of the Nottingham Dilator is 3 years (Indicated on product label with the following use-by symbol).
- Store the Nottingham Dilator at a temperature between 12°-35°C and a Humidity range of 30%-75%.
- Store in a dry, cool place. Avoid extended exposure to sun light.

Sterility – This product is Sterile unless the package has been opened or damaged

- The Nottingham Dilators have been sterilized by Exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change color from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct color.
- Exposure to high levels of Ethylene Oxide may result in presence of residual ETO which leads to Toxic Reaction in the body resulting in tissue damage of Urinary System.
- If the sterile package is damaged or possibly opened, do not use. Contact “Manufacturer or Distributor” and replace the product.
- The Nottingham Dilators are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

Directions for Use

- Open the package at the Chevron Side (‘V’ Side) of the pouch.
 - Suggested instructions for using Nottingham Dilators:
 - Pass the dilators over the previously placed guide wire while maintaining the guide wire position.
- NOTE- Dilators up to approximately 12 French may be passed through the working channel of the cystoscope. However, the telescope and inner scope elements must be removed – leaving the sheath – to accommodate the larger size. Duration of contact with the body is 1 day.

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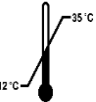


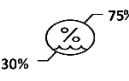
Removal Instructions

Retrieve cystoscopically by gently pulling on dilator or retrieval line with grasping forceps or equivalent. If resistance is encountered during removal of the dilator, stop and determine cause of resistance before proceeding.

Disposal Instructions

Dispose of all equipment, in appropriate containers. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Explanation of symbols used on label

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
	Catalogue Number		CE Mark		Do not Re sterilize		Country of Manufacture		Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use		Unique Device Identifier
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		Authorized Representative in the European community
	Humidity Limit								

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Bibliography

- Single Use Medical Device:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956268/Single_use_medical_devices.pdf
- EN ISO 15223-1:2021 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
- EN ISO 20417:2020 – Medical Devices- Information to be supplied by the manufacturer.