

Instruction for Use

CIC Catheter

Device Description

The CIC Catheter is a single-use device used in individuals with bladder disfunction caused by neurologic or non-neurologic causes to empty the bladder. Duration of Contact with the body is not more than 60 minutes. The configurations available include:

Family	Size (Fr.)	Length (cm)	Catalogue Number	Color
CIC Catheter (CIC)	10	15 35	AMPLCT013	Translucent
	12			
	14			
	16			
	18			

Intended Purpose

Clean intermittent catheter (CIC) is a device used to drain the urine from the bladder and is intended for use in individuals who cannot empty their bladder independently and is in need to perform self-catheterization to empty bladder at regular intervals. The device is intended for use by laypersons.

Performance Characteristics of the Device

CIC Catheters are sterile transparent catheters made of Poly Vinyl Chloride and involves inserting a thin, hollow tube into the bladder through urethra. The urine can be drained through the catheter into a toilet or urine bag and the catheter helps to maintain renal function by reducing the pressure in bladder, makes the bladder mucosa safer against pathogen invasion by improving bladder blood flow and minimize bladder degeneration due to chronic urinary retention.

Indications

Clean Intermittent Catheter is used in patients with:

- Neurogenic lower urinary tract dysfunction or Neurogenic Bladder caused by Cerebral palsy, Parkinson's disease, spina bifida or spinal cord injuries.
- Patients who have undergone bladder surgery.
- Central nervous system tumors (astrocytoma).
- Enlarged prostate (Benign Prostate Hyperplasia).
- Multiple sclerosis.
- Stroke

Contraindications

- Low bladder volume or Compliance
- Pressure sores/ external infection of the urethra
- Anatomical, functional or cognitive disorder that does not allow to perform CIC.
- Recurrent macrohematuria or urethrorrhagia
- Urethral Pain

Precautions & Warnings

Carefully read all instructions for use and product labelling. Do not use this product without reading and understanding the complete instructions enclosed herein. 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:

- The intended user of the device can be a urologist or health care provider/patient who are trained in the proper use of the device by a trained urologist specializing in the treatment of urinary system disorders and related urological procedures.
- Confirm the information on the label and that the product has not reached its expiration date and there is no damage to the packaging or device.
- Device is not recommended for use in patients with the above-mentioned contraindicated conditions.
- Store the CIC Catheter at a temperature between 12-35°C and a Humidity range of 30-70%.
- Store in a dry, cool place. Avoid extended exposure to sun light.
- Wear sterile rubber gloves, if desired, to keep hands sterile while performing this procedure or wash the hands using soap and water.
- Wash your genitals with soap and water or an antiseptic towelette. This lowers the infection risk.

Warnings:

- The device is for single use only.
- The product must not be re-used. Reusing single -use device can lead to potentially serious consequences for the patient such as Bio-contamination due to release of infectious agents from device into the body which further may result in Urinary Infection.
- Do not use the device if there is any indication that the sterility of the device has been compromised. If the sterile package is damaged or possibly opened, do not use. Contact "Manufacturer or Distributor" and replace the product.
- Do not re-process or re-sterilize, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to failure which, in turn, may result in patient injury.
- If you have not been properly trained in inserting a catheter, do not attempt.

Intended Patient Population

- The device is used in patients above the age of 18years in both male and female patients.
- Catheter of 35cm is used in males and 15cm is used in female patients.

Shelf-life

The shelf life of the CIC Catheters is 3 years (Indicated on product label with the use-by symbol).

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

- The CIC Catheters 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.
- The CIC Catheters are packed single. Product in each pack must be utilized immediately when opened.

Directions for use

- 1) Open the package from the Chevron side ('V' Notch) of the pouch.
- 2) Suggested instructions for using CIC Catheters:
- 3) Wash hands with antibacterial liquid or soap.
- 4) Wash the genitals with soap and water or an antiseptic towelette.
- 5) Select a clean and hygienic area where the catheter will be inserted.
- 6) Remove the catheter from its package being careful to keep it very clean.
- 7) Apply a water-based lubricant on the tip and top two inches of the insertion end of the catheter if needed.
- 8) Slowly insert the catheter with the tip facing up. Try to keep the catheter as straight as possible when you are inserting it, although you might have to rotate the catheter as you insert it.
- 9) Wait until urine begins to flow into the catheter. If the catheter slides out, even if you are getting urine flow coming from the catheter, the catheter is inserted wrong. Start the process again with a new catheter.

Instructions for Self-catheterization:

Regardless of gender, the steps for performing self-catheterization are generally the same. To perform self-catheterization:

- 1) Sit on the toilet (females may prefer to stand or squat over the toilet).
- 2) Use firm, gentle pressure to insert the lubricated end of the catheter into the urethra.
- 3) Hold the other end of the catheter over the toilet bowl or container (urine bag).
- 4) Then follow from step eight as mentioned above.
- 5) Consult a healthcare professional if you experience the following symptoms: Bladder Spasms (Sudden painful cramps and unexpected leaking of urine), Blood in urine (hematuria), difficulty inserting the catheter.





















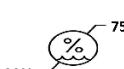
Removal Instructions

Gently remove the catheter once complete drainage of urine is ensured.

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

- Clean Intermittent Catheterization: <https://pubmed.ncbi.nlm.nih.gov/26956983/>
- Contraindications:
<https://pubmed.ncbi.nlm.nih.gov/29688647/#:~:text=There%20are%20a%20few%20contra,not%20allow%20frequent%20catheterization%2C%20patient>
- 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.