



INSTRUCTION FOR USE

1- PRODUCT DESCRIPTION

Smoothcath™ is a single-use, hydrophilic clean intermittent urinary catheter designed to ensure effective bladder emptying which comes in a sterile package containing a catheter, a water socket, and a protective sleeve. The catheter itself is made of medical-grade polyvinyl chloride (PVC), while the surface coating uses polyvinylpyrrolidone (PVP). This polymeric structure on the surface ensures that it becomes smooth and highly slippery. The hydrophilic nature of clean intermittent catheters eliminates the need for external lubricants, reducing microbial contamination. Additionally, it makes the insertion and removal of the catheter as smooth, easy, and painless as possible for the patient.

2- INDICATION FOR USE

In clean intermittent catheterization, the catheter is used to intermittently empty urine in patients with both neurogenic and non-neurogenic bladder disorders. The product is intended for prescription use only. Before using, be sure to receive guidance and training on the catheterization procedure from your healthcare professional.

3- CONTRAINDICATIONS

In patients with neurological pathologies who lack manual dexterity,
In patients with urethral strictures,
In patients with false passages,
In patients with autonomic dysreflexia.

4- COMPONENTS

Catheter: Medical PVC (Phthalate and DEHP-free)
Connector: Medical PVC (Phthalate and DEHP-free)
Surface Coating: PVP (K90)
Protective sleeve: Medical PVC Coil (Phthalate and DEHP-free)
Water Socket: Sterile water in aluminium foil
Package: Medical packaging paper, medical film
Box: Cardboard box
Contents: Catheter, protective sleeve, sterile water socket

5- STERILIZATION

The single-use hydrophilic urinary catheter is contained in medical packaging and is sterilized. The catheter is sterilized with Ethylene Oxide gas and the water socket is sterilized with gamma radiation. The product is for single use only. Do not re-sterilize and do not re-use.

6- INTENDED USE

Single-use Hydrophilic Urinary Catheter can be administered by a specialist doctor, healthcare staff or by individuals who have received training in this procedure.

7- STORAGE CONDITIONS

Store in a dry and dark place at the specified temperature range. Do not expose to organic solvents, ionizing radiation or ultraviolet light.

8- SHELF LIFE

When the specified conditions are maintained, the product has a shelf life of 3 years after the date of manufacture. Do not use products that have expired.

SmoothCath™ Guide Table

Fr.	06	08	10	12	14	16	18
mm	2.0	2.7	3.3	4.0	4.7	5.3	6.0
In.	0.079	0.105	0.131	0.158	0.184	0.210	0.236

Color



9- WARNINGS AND PRECAUTIONS

Store in a cool, dry, and dark place.
Do not re-sterilize the product or expose it to organic solvents.
Check the package and the product before use.
Do not use products past the expiration date indicated on the package.
Once the package is opened, the product must be used immediately.
The product is ready for use after the water sachet is burst. It must be used immediately after the water sachet is burst.
Use the catheter size recommended by your physician.

Consult Your Doctor or a Healthcare Facility If:

- You experience difficulty inserting the hydrophilic urinary catheter into the bladder,
- You have difficulty removing the hydrophilic urinary catheter from the bladder,
- You notice blood in the urine during catheterization.

If the Product Is Used More Than Once:

- The product's performance may deteriorate,
- The product's sterility may be compromised,
- The product may become deformed,
- The risk of urinary tract infection increases with reuse.

Hydrophilic Urinary Catheters are single-use products and must be used only once. After use, they should be disposed of in accordance with the Regulation on the Control of Medical Wastes.

The manufacturer assumes no responsibility for any situations arising from uses other than those described in this instruction manual.



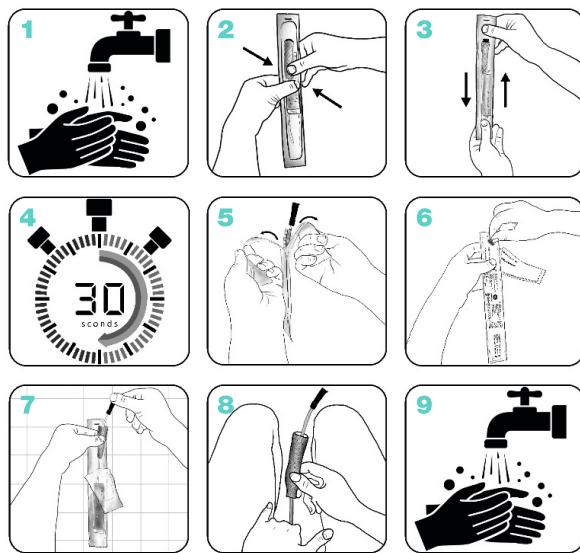
SmoothCath™

Hydrophilic Urinary Catheter With Water Sachet

INSTRUCTION FOR USE

SmoothCath™

Application Guide



10- APPLICATION

- 1- Wash your hands before starting the application.
- 2- Burst the water socket in the package.
- 3,4- Shake the pack for at least 30 seconds to ensure contact of the water with the catheter.
- 5- Open the package slightly from the top.
- 6- Remove the adhesive label on the back of the catheter pack and fix it on a desired surface.
- 7- Using the protective sleeve, advance the catheter through the urethra into the bladder until urine begins to flow.
- 8- Wait until the urine is completely emptied. Otherwise, remove the catheter in maximum 10 minutes. Remove the catheter slowly when the urine has stopped coming out. Dispose of the catheter according to standard institutional procedures for medical waste.
- 9- Wash your hands at the end of the application.

Caution

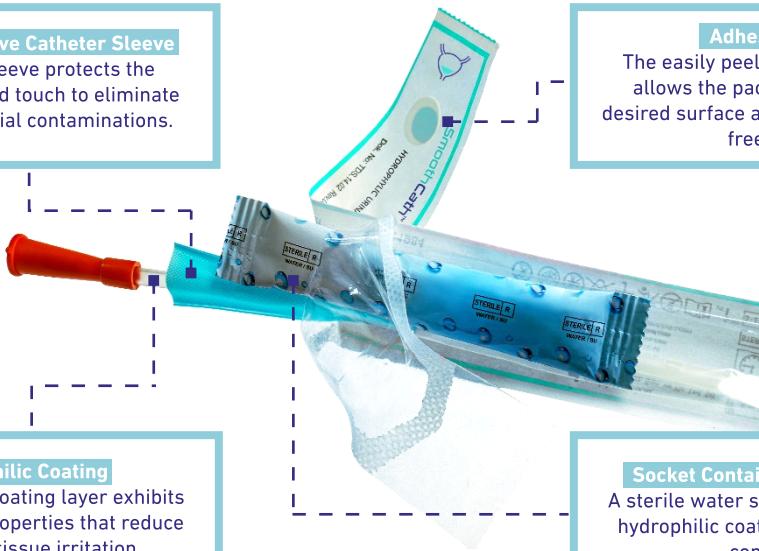
Dispose of used catheters according to standard medical waste procedures.

Hygienic Protective Catheter Sleeve

The Hygienic sleeve protects the catheter from hand touch to eliminate unwanted microbial contaminations.

Adhesive Patch

The easily peel-off adhesive patch allows the pack to adhere to the desired surface and leaves both hands free to use.



Hydrophilic Coating

The hydrophilic coating layer exhibits auto-lubricant properties that reduce friction and tissue irritation.

Socket Containing Sterile Water

A sterile water source to activate the hydrophilic coated layer in hygienic conditions.



Smoothcath
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MD	Medical Device
UDI	Unique Device Identifier (01)Device Identifier (17)Expiration Date (10) Lot Number (21) Serial Number
	Ethylene-oxide sterilized
	Water sachet is gamma sterilized
	Read instructions before use
	Do not use products with damaged packages
	Only for single use
	Cannot be re-sterilized
	Do not expose to sun
	Store at 5 °C to 30 °C
	Keep away from children
	Manufacturing site
	Production date
	Expiration date
	Store in dry place
LOT	Lot Number
REF	Reference Number
SN	Serial Number
SIZE	Catheter Size

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