Sterile Foley Catheter With Temperature Probe

Instructions For Use

[Intended use]

The Sterile Foley Catheter With Temperature Probe is used for routine clinical urethral catheterization for continuous monitoring of patients' bladder temperature with a monitor.

It is intended for temperature monitoring in patients which are catheterized because of fluid management problems, evaluation of urinary output, urine clearance following surgery or trauma involving pelvic organs, or obstruction and paralysis.

This device must be used in connection with the YSI 400 monitoring device (including its interface cable) to achieve temperature monitoring function. Follow "directions for use" of the patient temperature monitoring instrument.The device must be used by trained clinical professionals. Otherwise, product performance may be compromised or personal injury may occur. It is suitable for patient categories 2 years old and above. The applicable population is decided by the device size. Suitable sizes of urethral catheters MUST be chosen for different patient categories by medical professionals.

MRI safety information: details refer to MR conditional indicated.

[Performance]

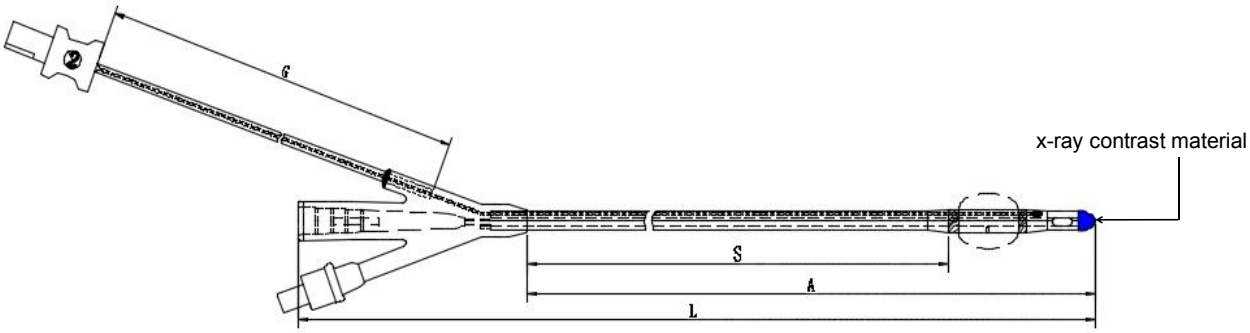
This product is made of harmless, non-toxic medical silicone and can be divided into two parts, namely the silicone foley catheter and the temperature probe. The shaft, balloon, tip, excretion funnel, inflation funnel, temperature measuring funnel, valve constitute the silicone foley catheter; the temperature probe consists of the thermal chip, wire and connector. All performance conforms to EN ISO 20696 & ISO 80601-2-56 standards. The product is sterile and sterilized by ethylene oxide, the residual amount of ethylene oxide should be less than or equal to 4mg/device.

In the range of 25°C to 45°C, temperature accuracy is ±0.1°C.

The operation mode is direct mode.

Time Response: Minimum measuring time ≤150s (water baths measurement).

[Specification]



Model (Fr)	OD. (mm)	Balloon Volume (mL)	S (mm)
6	2.0	3	150(Min.)
8	2.7	3-5	
10	3.3		
12	4.0	5-10	275(Min.)
14	4.7		
16	5.3		
18	6.0		
20	6.7		
22	7.3		
24	8.0		

[MRI Safety Information]

Non-clinical testing has demonstrated the “TempFoley Catheter” is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla**, with**
- Maximum spatial field gradient of 2,800 G/cm (28 T/m)
- **Maximum force product of** 50,000,000 G^2 /cm **(50 T^2 /m)**
- **Theoretically estimated** maximum whole body averaged (WBA) specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the “TempFoley Catheter” is expected to produce a maximum temperature rise of less than

2.1 °C **(2 W/kg, 1.5 Tesla) RF-related temperature increase with a background temperature increase of ≈1.8 °C (2 W/kg, 1.5 Tesla)**

2.2 °C **(2 W/kg, 3 Tesla) RF-related temperature increase with a background temperature increase of ≈2.1 °C (2 W/kg, 3 Tesla)**

after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 3.83 mm from the “TempFoley Catheter” when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

[Direction For Use]

1. Aseptic technique is to be applied during patient preparation and catheter care.
2. Open sterile packaging of the device.
3. Lubrication: Generously lubricate tip and shaft of catheter and also ensure balloon inflates and deflates effectively before insertion.
4. Insertion: Before intubation, the balloon should be pre-inflated to check whether the valve is in good condition and can be smoothly pumped or inflated. Then carefully insert the lubricated catheter into bladder (urine is excreted at this time) according to accepted medical techniques, and then a further 3-6cm to ensure balloon is also safely inside.
5. Inflation: Using a syringe without needle, inflate balloon with **sterile water,** Recommended volume is marked on funnel of catheter. Then Carefully attach drainage tubing and bag.
6. The catheter, drainage tubing and bag must be secured in place by adopting accepted medical techniques.
7. Temperature measuring: if necessary, connect the external end interface of the temperature probe with the adaptor cable of the monitor, and monitor the patient’s temperature in real time through the data displayed by the monitor.
8. Extraction: When taking out the catheter, first disconnect the temperature probe interface from the monitor, insert the empty syringe without a needle into the valve, and suck the sterile water in the balloon. When the volume of water in the syringe is close to the volume at the time of injection, the catheter can be pulled out slowly, or the body of the catheter can be cut off, so as to take out the catheter after rapid drainage.
9. Pull firmly at both connectors to disconnect. Never pull on the cable or wire.
10. Indwelling: Indwelling time depends on clinical needs and nursing requirements, but the maximum indwelling time shall not exceed **28 days**.

[Contraindication]

1. Acute urethritis, acute prostatitis;
2. Bladder spasms, bladder stones, kidney salts, urethral injury and tract infection, septicemia;
3. Pelvic fracture, test insert failure, electric burns from electrosurgical current;
4. Other unsuitable conditions considered by responsible medical professional.

[Precautions]

1. Do not use ointments or lubricants having petroleum base, i.e. paraffin oil as a lubricant will cause balloon to burst.
2. Suitable sizes of urethral catheters MUST be chosen for different patient category by medical professionals.
3. Prior to use, check whether the catheter is intact, whether the balloon leaks, and whether the suction is blocked. Whether the data displayed abnormal after the temperature probe connected with the monitor instrument.
4. Please check before use. If the valve does not inflate properly, replace the catheter immediately.
5. **DO NOT** use the product if following conditions are present:
   a) Beyond the 3-year shelf life;
   b) Packaging is opened, damaged or wet.
6. The process of intubation and extraction MUST be gentle and constant monitoring ensuring patients’ safety and well-being during retention period MUST be maintained. Avoid excessive pulling, and immediately inform clinical nursing staff to take corresponding measures if any discomfort.
7. **Professional medical techniques for patients of different age categories MUST be applied during foley catheterization.**
8. Strictly single use only. Repeated use can cause various infections.
9. This product should be operated by qualified medical staff and disposed according to the regulations of the hospital or local government after use.

10. This product is expected to be soaked in bodily fluids.
11. The balloon must be fully deflated before removing catheter.
12. Never use a needle to puncture the catheter wall for aspiration as leaks may occur.
13. Do not intertwine the cables, especially monitor cables with electrosurgical unit's cables.
14. This product is sterilized by ethylene oxide and has a valid period of 3 years from the date of production.
15. Applied Part: BF or CF, depending on the host device.
16. In the absence of verification, it should be avoided in the presence of electromagnetic interference to prevent the potential interference resulting in inaccurate temperature measurement performance.
17. Premature unpacking of me equipment could result in an unacceptable risk.
18. Do not place the product in an environment that exceeds the stated range, otherwise the performance and service life of the product will be affected.
19. The user shall be responsible for ensuring the compatibility between the probe and other equipment by referring to the Instructions For Use prior to usage. Otherwise, product performance may be compromised or personal injury may occur.
20. Notification of any serious incident related to the device shall be reported to the manufacturer and competent authority of the user and/or the member state where the patient is located.
21. After placing the catheter, please be careful to wipe away any lube gel from both the catheter and funnel, and ensure that the catheter funnel is really completely dry before connecting to the drainage tubing and bag.

[Clinical Benefit]

Provide the bladder temperature monitoring for patients during urine drainage.

[EMC PROMPT]

1.The product and the connected monitor equipment shall take special precautions regarding electromagnetic compatibility (EMC) and must be installed and used in accordance with the EMC information specified in this manual.

The product must use the following cables to meet the electromagnetic emission and anti-interference requirements:

Cable Name	Length
Adapter cable	<3 meters

2. Accessories, sensors and cables outside the specified range may increase the electromagnetic emission and / or decrease the electromagnetic immunity of the equipment.
3. The product and the connected monitor equipment cannot be used close to or stacked with other equipment. If necessary, it shall be closely observed and verified to ensure its normal operation in the used configuration.
4. When the input signal amplitude is lower than the minimum amplitude specified in the technical specifications, the measurement may be inaccurate.
5. Even if other equipment meets the emission requirements of CISPR, it may cause interference to the equipment.
6. Portable and mobile communication equipment will affect the performance of the equipment.
7. Any other RF radio frequency emission equipment may affect the equipment (for example, mobile phone, PDA, can have wireless work computer).

Guidance and manufacturer's statement —electromagnetic emission		
This product is intended to be used in the electromagnetic environment specified below, and the buyer or user shall guarantee that it is used in this electromagnetic environment.		
Launching test	Conformance	Electromagnetic environment - Guidelines
RF emission GB 4824（CISPR 11）	1 Group	Use RF energy only for its internal functions.Therefore, its RF emission is very low, and the possibility of interference to nearby electronic equipment is very small.
RF emission GB 4824（CISPR 11）	Class A	It is suitable for use in all facilities that are not domestic and are not directly connected to the public low-voltage power supply network of domestic residence.
Harmonic emission GB 17625.1	Not applicable	
Voltage fluctuation / flicker emission GB 17625.2（IEC 61000-3-3）	Not applicable	

Guidance and manufacturer's declaration— Electromagnetic Immunity Equipment is expected to be used in the following specified electromagnetic environment, and the buyer or user shall guarantee its use in this electromagnetic environment:			
Immunity test	IEC 60601 Test level	Coincidence level	Electromagnetic environment -Guidelines
Electrostatic discharge	±6kV contact discharge	±6kV contact discharge	The floor shall be wood, concrete or tile, and

(ESD) GB/T 17626.2 （IEC61000-4-2）	±8kV air discharge	±8kV air discharge	if the floor is covered with synthetic material, the relative humidity shall be at least 30%.
Electrical fast transient pulse group GB/T 17626.4 （IEC61000-4-4）	±2kV to power line ±1kV for input / output line	Not applicable	Not applicable
Surge GB/T 17626.5 （IEC61000-4-5）	±1kV line to line ±2kV line to ground	Not applicable	Not applicable
Voltage sag, short-time interruption and voltage change on the power input line GB/T 17626.11 （IEC61000-4-11）	< 5% UT for 0.5 cycles (> 95% sag on UT) 40% UT for 5 cycles (60% sag on UT) 70% UT for 25 cycles (30% sag on UT) < 5% UT for 5s (> 95% sag on UT)	Not applicable	Not applicable
Power frequency magnetic field (50 / 60Hz) GB/T 17626.8 （IEC 61000-4-8）	3 A/m	3 A/m	The power frequency magnetic field should have the power frequency magnetic field level characteristic in the typical business or hospital environment.
Note:UT refers to the AC network voltage before applying the test voltage.			

Guidance and manufacturer’s declaration - Electromagnetic Immunity

Equipment is expected to be used in the following specified electromagnetic environment, and the buyer or user shall guarantee its use in this electromagnetic environment:

Immunity test	IEC60601 Test level	Coinciden ce level	Electromagnetic environment - Guidelines
RF ncyconduction GB/T 17626.6（ IEC61000- 4-6） RF cy radiation GB/T 17626.3（ IEC61000- 4-3）	3 V rms 150kHz - 80MHz 3 V/m 80MHz - 2.5GHz	3 V rms 3 V/m	Portable and mobile RF communication equipment shall not be used closer to any part of the equipment than the recommended isolation distance, including cables.The distance is calculated by the formula corresponding to the transmitter frequency Recommended separation distance D = $1.2\sqrt{P}$ 150 kHz ～ 80 MHz D = $1.2\sqrt{P}$ 80MHz-800MHz D = $2.3\sqrt{P}$ 800MHz-2.5GHz Formula: P -- according to the maximum rated output power of transmitter provided by transmitter manufacturer, in watts (W); D -- recommended isolation distance, in meters (m). The field strength of fixed RF transmitter is determined by electromagnetic field survey, and it should be lower than the compliance level in each frequency range.[AB] Interference may occur near equipment marked with the following symbols. 
Note 1:In the frequency of 80MHz and 800MHz, the formula of higher frequency band is adopted. Note 2:These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection of buildings, objects and human body.			
[A]-Fixed transmitters, such as base stations for wireless (cellular / cordless) telephones and ground mobile radios, amateur radios, am and FM radio broadcasts, and television broadcasts, are theoretically unpredictable in field strength.In order to evaluate the electromagnetic environment of fixed RF transmitter, the survey of electromagnetic field should be considered.If the measured field strength of the equipment is higher than the applicable RF compliance level, observe the equipment to verify its normal operation.If abnormal performance is observed, additional measures may be necessary, such as reorienting or repositioning the equipment.			

[B].In the whole frequency range of 150khz-80mhz, the field strength should be lower than 3V / m.

Recommended isolation distance between portable and mobile RF communication equipment and equipment:

Equipment It is expected to be used in electromagnetic environment with controlled RF radiation disturbance.According to the maximum rated output power of communication equipment, the buyer or user can prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communication equipment (transmitter) and equipment as recommended below.

Maximum rated output power of transmitter W	Isolation distance corresponding to different frequencies of transmitter / M		
	150kHz -80MHz $D=1.2\sqrt{P}$	80MHz - 800MHz $D=1.2\sqrt{P}$	800MHz -2.5GHz $D=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the maximum rated output power of transmitter not listed in the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where p is the maximum rated output power of transmitter provided by the transmitter manufacturer.In watts (W).

Note 1:At the frequency points of 80MHz and 800MHz, the formula of higher frequency band is adopted.

Note 2:These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection of buildings, objects and human body.

[Symbol]

Refer to instruction manual/ booklet

Do not re-use

Latex free

Do not use if package is damaged and consult instructions for use

Medical device

Manufacturer

Batch code

Date of manufacture

Use-by date

Model number

Keep dry

Keep away from sunlight

Storage and transportation humidity limitation

Storage and transportation temperature limitation

Sterilized using ethylene oxide Single sterile barrier system with protective packaging inside

Compliance to Medical Devices Regulation 2017/745

Authorized representative in the European Community / European Union

Comply with the requirements of directive 2012/19/EU waste electrical electronic equipment

Fragile, handle with care

MR Conditional

Stacking limit by number

Operating,Storage and transportation atmospheric pressure limitation

[Warning]

1. Please do not use if the package is damaged or opened.
2. The injection of sterile water shall not exceed the nominal capacity shown on the catheter (ml).
3. To disconnect, grasp both connectors firmly and pull. Do not pull on cable or wire as this will cause serious injuries.
4. The temperature probe wires might be protruded from the catheter, which placed the patient at risk for significant urethral injury. This can happen if the medical staff inserted and removed the tube roughly, or even if the patient is moving, worried or if it is a child pulling. So the process of intubation and extraction MUST be gentle. When the catheter indwelling in the human body, the tube outside human body can be fixed with adhesive tape to avoid deformation and injury caused by the pulling of the tube caused by human activities. And It is necessary to constant monitoring ensuring patients' safety and well-being during retention period MUST be maintained.

[Operating, Storage and Transportation]

Operating environment: 5℃ to 40℃, 20% to 85%RH, 70kPa~106kPa.

Storage and transportation environment: -20℃ to 55℃, 10% to 93% RH, 70kPa~106kPa non-corrosive gas and well-ventilated clean room.

The means of transport should be clean and hygienic, shaded from sunlight and moisture.

[Instructions For Use Download]

Access download link in our company website listed below.

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