



SILICONE FOLEY BALLOON CATHETER

The Right Choice for Quality Catheters



SILICONE FOLEY BALLOON CATHETER

Fortune[®] Silicone 2 way Foley balloon Catheter Features:

- 100% medical grade silicone for superior biocompatibility.
- Transparent medical grade silicone tube allows easy visual inspection and fluid observation.
- X-ray opaque line allows for confirmation of intubated tube using X-ray.
- Soft and uniformly inflated balloon makes the tube sit well against the bladder.
- Smooth round shaft can minimize trauma during insertion and withdrawal.
- 6FR, 8FR and 10FR Pediatric Foley Catheter has disposable stylet for easy insertion.
- Includes an individual sterilized packed Catheter Spigot.
- Sterilized double packaging.
- Firm yet flexible tip designed to aid insertion.
- Recommended usage up to 90 days for 4833 series, of which balloon is more durable recommended usage up to 29 days for 182X/1856/1830/4822/4856 series.

- A** Pediatric
- B** Standard, 5-10 cc/ml
- C** Standard, 20-30 cc/ml
- D** Female
- E** Catheter Spigot
- F** Tiemann Tip



SPECIFICATIONS

2-Way Foley Balloon Catheter, Pediatric:

| REF. No. | Size | Balloon | Length | Description |
|-----------|-------|-------------|--------|--|
| 1821-0506 | 6 FR | 1-1.5 cc/ml | 330 mm | Stylet X-ray opaque line Catheter spigot |
| 1821-0508 | 8 FR | 2-3 cc/ml | | |
| 1821-0510 | 10 FR | 3-5 cc/ml | | |
| 1821-0606 | 6 FR | 1-1.5 cc/ml | 330 mm | Metal Stylet X-ray opaque line Catheter spigot |
| 1821-0608 | 8 FR | 2-3 cc/ml | | |
| 1821-0610 | 10 FR | 3-5 cc/ml | | |



1821-05XX/1821-06XX

SILICONE FOLEY BALLOON CATHETER

2-Way Foley Balloon Catheter, Standard, 5-10 cc/ml:

| REF. No. | Size | Balloon | Length | Description |
|-----------|-------|------------|--------|--------------------------------------|
| 1822-0512 | 12 FR | | | |
| 1822-0514 | 14 FR | | | |
| 1822-0516 | 16 FR | | | |
| 1822-0518 | 18 FR | 5-10 cc/ml | 420 mm | X-ray opaque line Catheter spigot |
| 1822-0520 | 20 FR | | | |
| 1822-0522 | 22 FR | | | |
| 1822-0524 | 24 FR | | | |
| 1822-0526 | 26 FR | | | |



1822-05XX

2-Way Foley Balloon Catheter, Standard, 20-30 cc/ml:

| REF. No. | Size | Balloon | Length | Description |
|-----------|-------|-------------|--------|--------------------------------------|
| 1823-0514 | 14 FR | | | |
| 1823-0516 | 16 FR | | | |
| 1823-0518 | 18 FR | | | |
| 1823-0520 | 20 FR | 20-30 cc/ml | 420 mm | X-ray opaque line Catheter spigot |
| 1823-0522 | 22 FR | | | |
| 1823-0524 | 24 FR | | | |
| 1823-0526 | 26 FR | | | |



1823-05XX

2-Way Foley Balloon Catheter, Female:

| REF. No. | Size | Balloon | Length | Description |
|-----------|-------|------------|--------|--------------------------------------|
| 1824-0512 | 12 FR | | | |
| 1824-0514 | 14 FR | | | |
| 1824-0516 | 16 FR | | | |
| 1824-0518 | 18 FR | 5-10 cc/ml | 250 mm | X-ray opaque line Catheter spigot |
| 1824-0520 | 20 FR | | | |
| 1824-0522 | 22 FR | | | |
| 1824-0524 | 24 FR | | | |
| 1824-0526 | 26 FR | | | |



1824-05XX

2-Way Foley Balloon Catheter, Tiemann Tip:

| REF. No. | Size | Balloon | Length | Description |
|-----------|-------|------------|--------|---|
| 1856-0210 | 10FR | 3-5 cc/ml | | |
| 1856-0212 | 12 FR | | | |
| 1856-0214 | 14 FR | | | |
| 1856-0216 | 16 FR | 5-10 cc/ml | 420 mm | Tiemann tip X-ray opaque line Catheter spigot |
| 1856-0218 | 18 FR | | | |
| 1856-0220 | 20 FR | | | |
| 1856-0222 | 22 FR | | | |
| 1856-0224 | 24 FR | | | |



1856-02XX

Catheter Spigot:

| REF. No. | Size | Description |
|-----------|-----------|---|
| 1820-0000 | Universal | ABS Sterilized packaging 50 pcs/box |



1820-0000

SILICONE FOLEY BALLOON CATHETER

Fortune[®] Silicone 3-Way Foley Catheter Features:

- 100% medical grade silicone for superior biocompatibility.
- Transparent tube with X-ray opaque line.
- A soft and uniformly inflated balloon makes the tube sit well against the bladder.
- 3-Way design with an attached plug on the irrigation funnel.
- Tapered Central funnel could be connected with irrigation bags.
- Includes an individual sterilized packed Catheter Spigot.
- Sterilized double packaging.
- The tip of 3-way Foley Balloon Catheter with open hole, it could be used together with guide wire for difficulty in catheterization.

A Silicone 3-Way Foley Balloon



SPECIFICATIONS

3-Way Foley Balloon Catheter

| REF. No. | Size | Balloon | Length | Description |
|-----------|-------|-------------|--------|--|
| 1830-0514 | 14 FR | | | |
| 1830-0516 | 16 FR | | | |
| 1830-0518 | 18 FR | | | |
| 1830-0520 | 20 FR | 20-30 cc/ml | 420 mm | Attached plug on flushing port X-ray opaque line Catheter spigot |
| 1830-0522 | 22 FR | | | |
| 1830-0524 | 24 FR | | | |
| 1830-0526 | 26 FR | | | |



1830-05XX

SILICONE FOLEY BALLOON CATHETER

Fortune® Foley Integrated Balloon Catheter:

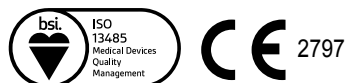
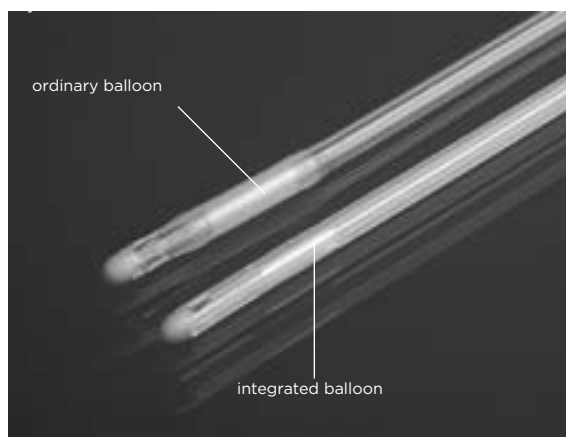
Catheter with Integrated Balloon was designed to minimize the discomfort during catheterization procedure. Compare to the ordinary balloon, due to its thickness, creates a conjunction edge after adhered onto the tubing shaft. This conjunction edge between balloon and shaft will eventually increase patient discomfort during insertion and withdrawal.

Fortune® Integrated Balloon Catheter is invented to eliminate the uneven edge out of ordinary balloon. Patented balloon is integrated into the catheter shaft, creates “complete” smooth surface. No conjunction edge between balloon and shaft is formed, which minimizes the friction within the urethra and reduced patient discomfort. Recommended usage up to 90 days for 4833 series, of which balloon is more durable! recommended usage up to 29 days for 4822/4856 series.

Advantages:

- Patented balloon integrated into the shaft.
- Complete smooth surface.
- Reduce friction within the urethra
- Reduce trauma and secondary harm.
- Reduce discomfort during insertion and withdrawal.
- Reduce accumulation of urine sediment.
- The 4833 series has been successfully passed the long-term balloon test, the balloon filled with 10cc sterile water performed no deflation or rupture after being immersed in the simulate urine for 90 days.

- A Silicone Foley Integrated Balloon Catheter**
- B Silicone Foley Integrated Balloon Catheter, Tiemann Tip**
- C Foley Integrated Balloon Catheter, Long-Term balloon**



SILICONE FOLEY BALLOON CATHETER

SPECIFICATIONS

Foley Integrated Balloon Catheter:

| REF. No. | Size | Balloon | Length | Description |
|-----------|-------|------------|--------|--|
| 4822-0512 | 12 FR | | | |
| 4822-0514 | 14 FR | | | |
| 4822-0516 | 16 FR | | | |
| 4822-0518 | 18 FR | 5-10 cc/ml | 420 mm | Integrated balloon X-ray opaque line Catheter spigot |
| 4822-0520 | 20 FR | | | |
| 4822-0522 | 22 FR | | | |
| 4822-0524 | 24 FR | | | |
| 4822-0526 | 26 FR | | | |



4822-05XX

Foley Integrated Balloon Catheter, Tiemann Tip:

| REF. No. | Size | Balloon | Length | Description |
|-----------|-------|------------|--------|---|
| 4856-0212 | 12 FR | | | |
| 4856-0214 | 14 FR | | | |
| 4856-0216 | 16 FR | | | |
| 4856-0218 | 18 FR | 5-10 cc/ml | 420 mm | Tiemann tip Integrated balloon X-ray opaque line Catheter spigot |
| 4856-0220 | 20 FR | | | |
| 4856-0222 | 22 FR | | | |
| 4856-0224 | 24 FR | | | |



4856-02XX

Foley Integrated Balloon Catheter, Long-Term balloon

| REF. No. | Size | Balloon | Length | Description |
|-----------|-------|------------|--------|--|
| 4833-0512 | 12 FR | | | |
| 4833-0514 | 14 FR | | | |
| 4833-0516 | 16 FR | | | |
| 4833-0518 | 18 FR | 5-10 cc/ml | 420 mm | Integrated , long term balloon X-ray opaque line Catheter spigot |
| 4833-0520 | 20 FR | | | |
| 4833-0522 | 22 FR | | | |
| 4833-0524 | 24 FR | | | |
| 4833-0526 | 26 FR | | | |

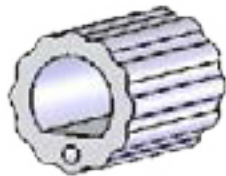


4833-05XX

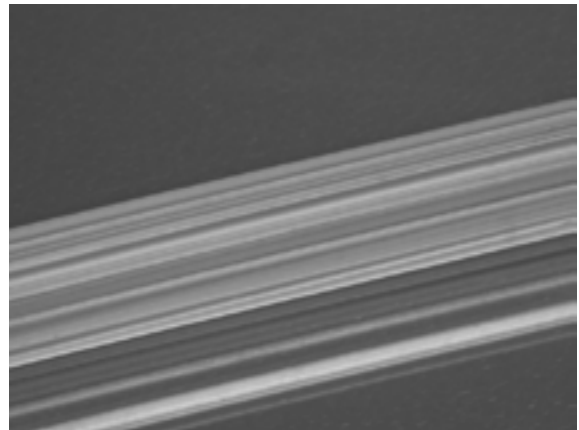
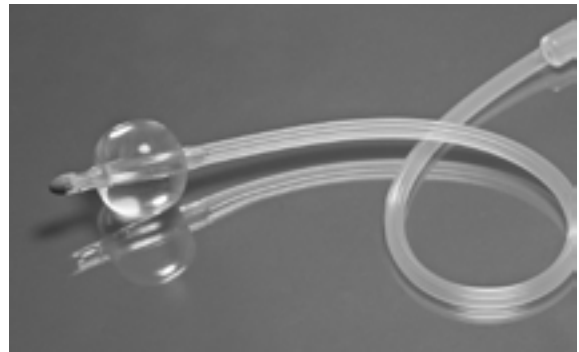
SILICONE FOLEY BALLOON CATHETER ,GROOVED

Fortune® Silicone 2 way Foley balloon grooved Catheter Features:

- 100% medical grade silicone for superior biocompatibility.
- Transparent medical grade silicone tube allows easy visual inspection and fluid observation.
- Grooved catheter was designed to minimize the discomfort during catheterization procedure. With ribs on outer profile of tubes, lubricity of catheter is increased, facilitating easy catheter removal.
- Soft and uniformly inflated balloon makes the tube sit well against the bladder.
- Includes an individual sterilized packed Catheter Spigot.
- Sterilized double packaging.



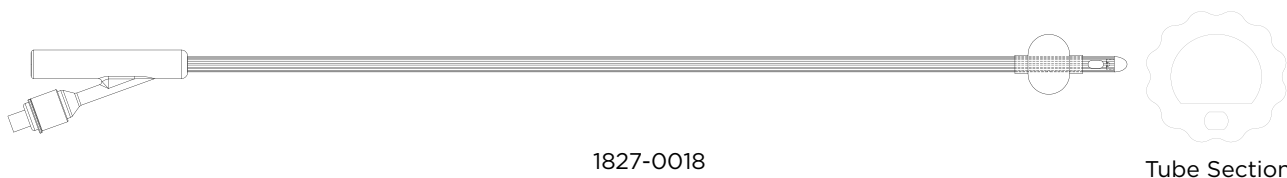
Grooved Tube



SPECIFICATIONS

Silicone 2-way Foley balloon catheter, grooved tube

| REF. No. | Size | Balloon | Length | Description |
|-----------|-------|------------|--------|-------------------------------|
| 1827-0012 | 12 FR | | | |
| 1827-0014 | 14 FR | | | |
| 1827-0016 | 16 FR | | | |
| 1827-0018 | 18 FR | 5-10 cc/ml | 420 mm | grooved tube, Catheter spigot |
| 1827-0020 | 20 FR | | | |
| 1827-0022 | 22 FR | | | |
| 1827-0024 | 24 FR | | | |



1827-0018

Tube Section

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4


No. **CE 588902**
Issued To: **Fortune Medical Instrument Corp**
6F., No. 29, Sec. 2, Jhongjheng E.Rd.,
Danshuei Dist,
New Taipei City
251
Taiwan

In respect of:

The design, manufacture and final inspection of sterile urological catheters and accessories, drainage tube and accessories, endotracheal tube, tracheostomy tube, reservoir, gastrointestinal tube and accessories, silicone surgical ruler and silicone vessel ID loops and non-sterile laryngeal mask tube.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: 2012-08-27

Date: 2018-10-05

Expiry Date: 2023-09-24

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: Fortune Medical Instrument Corp.
6F., No. 29, Sec. 2
Jhongjheng E. Rd.
Danshuei Dist.
New Taipei City
251
Taiwan

Holds Certificate No: **MD 588797**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture and sales of sterile urological catheters and accessories, catheter spigot, drainage tube and accessories, endotracheal tube, tracheostomy tube, reservoir, epistaxis device, gastrointestinal tube and implantable vascular access port and accessories, silicone surgical ruler and silicone vessel ID loops, and of non-sterile laryngeal mask tube, resuscitator and accessories, vacuum suction and accessories, tracheal tube fixation device and scar management products.
The provision of ethylene oxide sterilization services in accordance with EN ISO 11135:2014.

For and on behalf of BSI:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2012-08-23

Latest Revision Date: 2019-07-31

Effective Date: 2019-08-09

Expiry Date: 2022-08-08

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Certificate No: **MD 588797**

Location

Registered Activities

Fortune Medical Instrument Corp.
6F, No. 29, Sec. 2
Jhongjheng E. Rd.
Danshuei Dist.
New Taipei City
251
Taiwan

The sales of sterile urological catheters and accessories, catheter spigot, drainage tube and accessories, endotracheal tube, tracheostomy tube, reservoir, epistaxis device, gastrointestinal tube and implantable vascular access port and accessories, silicone surgical ruler and silicone vessel ID loops, and of non-sterile laryngeal mask tube, resuscitator and accessories, vacuum suction and accessories, tracheal tube fixation device and scar management products. The sales of ethylene oxide sterilization services in accordance with EN ISO 11135:2014.

Fortune Medical Instrument Corp.
No. 256, Changchun 2nd Rd.
Jhongli Dist.
Taoyuan City
320
Taiwan

The design, development, manufacture and sales of sterile urological catheters and accessories, catheter spigot, drainage tube and accessories, endotracheal tube, tracheostomy tube, reservoir, epistaxis device, gastrointestinal tube and implantable vascular access port and accessories, silicone surgical ruler and silicone vessel ID loops, and of non-sterile laryngeal mask tube, resuscitator and accessories, vacuum suction and accessories, tracheal tube fixation device and scar management products. The provision of ethylene oxide sterilization services in accordance with EN ISO 11135:2014.

Original Registration Date: 2012-08-23

Effective Date: 2019-08-09

Latest Revision Date: 2019-07-31

Expiry Date: 2022-08-08

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +886 (02)2656-0333.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.