

BILIARY CATHETERS SINGLE DOUBLE AND TRIPLE LUMEN

CE marking: 2000

Products references:

- simple lumen catheters: range 340000
- double lumen catheters: range 540000
- triple lumen catheters: range 640000

Caution: this product contains natural rubber latex which may cause allergic reactions. Only references ending with “LF” do not contain natural latex rubber.

Product sterilized by ethylene oxide. Sterile product as long as the packaging hasn't be opened, damaged or broken. Single use product.

CONTRAINDICATIONS:

- **This catheter is not made to diagnose, to watch or correct a heart or central circulation system failure by direct contact with the central circulatory system.**
- **The biliary catheter should not be used outside the biliary system.**
- **The biliary catheter is not recommended for the removal of fibrous, adherent, or calcified material (e.g. chronic clot, atherosclerotic plaque). The catheter is not designed to withstand the additional pull force needed to remove these materials.**

WARNINGS:

- **Balloon rupture and catheter separation as a result of excessive pull force applied to remove adherent material are the most frequent causes of reported failures. The possibility of balloon rupture must be taken into account when considering the risks involved in any procedure.**
- **To minimize the risk of vessel damage, balloon rupture, or tip detachment, do not exceed the maximum recommended inflation volume and pull force for each size catheter (see Table A and B).**
- **Use of a highly viscous or particulate contrast medium is not recommended for balloon inflation because the inflation lumen may become occluded.**
- **To minimize the risk of infection, it is recommended to do preventive antibiotic therapy.**

BILIARY CATHETER USE:

The biliary catheter is indicated for digestive surgery interventions to clear of obstructions biliary ducts in particular the choledoque. The catheter is intended to be inserted through biliary duct, with deflated balloon, until the suspected occlusion site is reached. Then, the catheter tip may be advanced further with the balloon deflated through the occlusion site. Stone removal is achieved by inflating the distal balloon with sterile psychological serum and subsequently withdrawing the catheter tip.

Check during the withdrawal procedure that the balloon diameter is constantly in contact with the biliary duct walls.

For double lumen catheters, the stone radio-visibility can be improved by inflating the balloon then injecting a product of contrast by the distal tip. Double and triple lumen 200cm catheters are used for endoscopic removal of stones in the biliary system, and to inject contrast solution. Infusion of any sterile liquid may be performed, with the balloon inflated or deflated, through the distal orifice.

BILIARY CATHETER DESCRIPTION:

The single, double and triple lumen biliary catheters are marked in 1 cm graduation to gauge the length of insertion and, printed on the proximal end, its naming, size and the maximal volume to inject in the balloon.

The distal portion of the catheter contains a latex section that inflates to form a balloon.

For the double lumen catheters, the derivation branch (white) is connected to the balloon and the main branch (which colour indicates the catheter size) allows the injection of the necessary solutions.

Concerning triple lumen catheters, the principal lumen (transparent) allows the insertion of a guide wire, and secondary lumens are for irrigation and balloon inflating. They are identified by the size of the catheter and respectively “irrigation” and the maximum volume allowed in the balloon.

WARNING: Our catheter is designed to provide the surgeon with a variety of functional options for a wide range of surgical procedures. Therefore, the procedural approach, surgical technique, selection of infusate and method of use must be left to the discretion of the individual surgeon using the device: the medical judgement of the physician must be exercised at all time.

A size range of catheters is available in order to accommodate a variety of the vessels diameters and length (see table A).

DIRECTION FOR USE: CATHETER PRIMING

Remove the protection and mandrel from catheter before use by unrolling and keeping it as straight as possible.

The catheter should be primed before use. In case of double and triple lumen, each lumen should be primed before use.

- 1- Select the appropriate size Luer Lock syringe for use with the catheter (see the balloon maximal volume noted next to the hub).
- 2- Use liquid prime which is sterile and blood compatible (for example sterile physiological serum). Fill the syringe with liquid prime.

CAUTION: It is not recommended to use air to inflate the balloon

- 3- Fix the syringe to the catheter Luer Lock connection. For the double lumen, connect it to the white derivation branch hub. For triple lumen connect it to the derivation branch with a volume indicated in mL.
- 4- Hold the catheter vertically with distal tip toward the ground and slowly inject liquid prime into the catheter.

- 5- Remove air from the catheter by tapping it so that the air will return up into the syringe. Produce vacuum with the syringe. Do it again until air is totally eliminated from the catheter body.
- 6- During priming, inspect the inflated balloon and catheter body. A balloon which does not inflate, leaks, or is strongly asymmetric (out of centre) should not be used.
- 7- Once the catheter is fully primed, the syringe is disconnected from the catheter and all residual contents are expelled from the syringe.
- 8- The syringe is then refilled with appropriate volume of liquid (see table A) and the syringe reconnected. The catheter is ready for use.
- 9- Insert the catheter with deflated balloon inside the canal.
- 10- Under radiosopic control, place the deflated balloon above the gallstone. If there is more than one gallstone, extract them one by one.
- 11- Check that the balloon is in the right position and inflate it with sterile solution. Extract the gallstone along the open passage.
- 12- In the case of 200cm catheters, while keeping the prop up of the endoscope open, keep the balloon slightly inflated. Never pu excessive pressure on the bulb during the gallstone extraction. If the gallstone doesn't come out easily, evaluate the necessity of doing o sphincterotomy.
- 13- Balloon should be deflated, when it is visible on the endoscope inside the duodenum.

Repeat the extraction procedure, one stone at a time, until the passage is free.

WARNING: Exceeding the maximum recommended liquid volume for each size catheter greatly increases the possibility of balloon rupture. Balloon rupture is sensed by a decrease in resistance on the syringe during inflation procedures. If balloon rupture occurs, the catheter should be withdrawn.

WARNING: In the event successive injections of different liquids are necessary, it is recommended to rinse the catheter and the syringe with sterile physiological serum, to avoid any medicinal interaction risk.

WARNING: Do not resterilize

WARNING: Store in a cool and dry place with ambient temperature. Avoid extreme temperatures (+5° C and >+30° C) and humidity.

Avoid exposition to intense lights sources (solar light, fluorescent tube...) to preserve the balloon.

Conserve in the original packaging.

WARNING: Read carefully instructions before use.

WARNING: Shelf life - Use this catheter before the expiration date indicated on the packaging.

WARNING: Dispose of used devices according to local regulations for contaminated waste.

The materials of the catheter are: tube & hub = TPE, balloon = latex or polyisoprene (for references LF), protector tube = PE, pouch = PGL + PET / PE, rod tube = ABS + MABS + Tyvek ®

BILIARY CATHETERS SINGLE DOUBLE AND TRIPLE LUMEN
TABLE A: SINGLE AND DOUBLE LUMEN STANDARD BILIARY CATHETERS

Other dimensions can be realised upon request

We recommend to use a 3 ml syringe capacity to inflate our catheters

REFERENCES	COLOUR CODE	OUTER DIAMETER	USEABLE LENGTH	MAXIMUM RECOMMENDED LIQUID VOLUME	APPROXIMATE DIAMETER OF INFLATED BALLOON	COMPATIBLE GUIDEWIRE (INCH)
SINGLE LUMEN BILIARY CATHETERS						
340423 – 40 – 60 - 80	Red	4F (1,35 mm)	23 cm - 40 cm - 60 cm - 80 cm	0,75 ml	8 mm	-
340523 – 40 – 60 - 80	White	5F (1,70 mm)	23 cm - 40 cm - 60 cm - 80 cm	1,50 ml	10 mm	-
340623 – 40 – 60 - 80	Blue	6F (2,00 mm)	23 cm - 40 cm - 60 cm - 80 cm	2,00 ml	13 mm	-
DOUBLE LUMEN BILIARY CATHETERS						
540440 – 60 – 80	Red	4F (1,35 mm)	40 cm - 60 cm - 80 cm	0,75 ml	8 mm	-
540540 – 60 – 80	White	5F (1,70 mm)	40 cm - 60 cm - 80 cm	1,50 ml	10 mm	.018
540640 – 60 – 80	Blue	6F (2,00 mm)	40 cm - 60 cm - 80 cm	2,00 ml	13 mm	.018
540740 – 60 – 80	Yellow	7F (2,35 mm)	40 cm - 60 cm - 80 cm	2,50 ml	14 mm	.025
5405200	White	5F (1,70 mm)	200 cm	1,50 ml	10 mm	.025
5407200	Yellow	7F (2,35 mm)	200 cm	2,50 ml	14 mm	.035
5405201 (with ring)	White	5F (1,70 mm)	200 cm	1,50 ml	10 mm	.025
5407201 (with ring)	Yellow	7F (2,35 mm)	200 cm	2,50 ml	14 mm	.035

TABLE B : TRIPLE LUMEN STANDARD BILIARY CATHETERS

Color : transparent.

REFERENCES	WIRE GUIDING	EXTERNAL DIAMETER	USEABLE LENGTH	INJECTION APERTURE	MATERIEL	BALLOON LENGTH (MM)	MAXIMAL PULL STRENGTH (N)
6407202P	LONG	7 F (2,35 mm)	200 cm	ABOVE	LATEX	12	15
6407202PC	DISTAL	7 F (2,35 mm)	200 cm	ABOVE	LATEX	12	15
6407202D	LONG	7 F (2,35 mm)	200 cm	UNDER	LATEX	12	15
6407202DC	DISTAL	7 F (2,35 mm)	200 cm	UNDER	LATEX	12	15
6407202PLF	LONG	7 F (2,35 mm)	200 cm	ABOVE	LATEX FREE	12	15
6407202PCLF	DISTAL	7 F (2,35 mm)	200 cm	ABOVE	LATEX FREE	12	15
6407202DLF	LONG	7 F (2,35 mm)	200 cm	UNDER	LATEX FREE	12	15
6407202DCLF	DISTAL	7 F (2,35 mm)	200 cm	UNDER	LATEX FREE	12	15

TABLE C : FILLING VOLUMES AND CORRESPONDING DIAMETERS (TRIPLE LUMEN BILIARY CATHETER)

VOLUME (ML)	0,5	0,8	1,5
DIAMETER (MM)	10	12	14