

Summary of Safety and Effectiveness: Circon-Surgitek Double Pigtail Ureteral Stent

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1. Applicant's Name
Circon-Surgitek Corporation (formerly known as Cabot-Surgitek, Surgitek or Medical Engineering Corporation)

3. Owner/Operator's Name and Establishment Registration Number:
Owner/Operator's Address:
Circon Corporation
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Santa Barbara, CA 93117
Establishment Registration Number 9920160

2. Contact Person, Contact Person's Address, Telephone Number and Establishment Registration Number:
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3. Manufacturing Site Address and Establishment Registration Number:
Circon-Surgitek
3037 Mt. Pleasant Avenue
Racine, WI 53404
Establishment Registration Number 2124979

4. Device Trade/Proprietary Name:
Circon-Surgitek Classic Double Pigtail Ureteral Stent

5. Classification Name and Panel Classification Number:
Classification Name: Ureteral Splint
Classification Code; 78FAD
Regulation Number: 21CFR §876.4620
Common/Usual Name: Ureteral Stent

6. Marketed Devices Used for Substantial Equivalence:
The Circon-Surgitek Classic Double Pigtail Ureteral Stent is substantially equivalent to Ureteral Stents which were available prior to May 28, 1976 and to devices marketed after May 28, 1976 and were determined as substantially equivalent by the US FDA. The Circon-Surgitek Classic Double Pigtail Ureteral Stent is substantially equivalent to the following devices; 1) the Microvasive Mardis Stent [K860267], 2) the Cook Double Pigtail Stent [K930731]; 3) the Circon-Surgitek Lubri-Flex [K905289] and 4) the Circon-Surgitek Quadra-Coil™ [K946296].

7. Device Description and Intended Use of the Marketed Device:

Indications for Use

The Surgitek Classic Double Pigtail Ureteral Stent is an indwelling device used to provide drainage from the kidney to the bladder and stenting of the ureter without external catheters. The stent may be placed using endoscopic, percutaneous or open procedures.

Device Description

The Circon-Surgitek Classic Double Pigtail Ureteral Stent is a ureteral stent without a hydromer coating. The function of the double pigtail ureteral stent is to provide drainage from the kidney to the bladder and stenting of the ureter without the aid of internal catheters.

The Circon-Surgitek Classic Double Pigtail Ureteral Stent has a flexible pigtail curl at both the proximal (kidney) and distal (bladder) end of the stent. The kidney curl of the double pigtail is similar to the Circon-Surgitek Lubri-Flex™ kidney curl [K905289] while the bladder curl is similar to the Circon-Surgitek Multi-Flex [K913928]. These curls minimize upward and downward migration of the device. The curls at each end are formed in opposite directions from each other. The proximal kidney curl hooks, laterally into the lower colon or renal pelvis while the distal bladder curl curves medially into the bladder. The kidney curl, located at the proximal end of the device, is easily distinguished by the open tapered tip (or tail) which extends beyond the curl. The bladder curl, located at the distal end of the device, is distinguished by its open blunt end which does not extend beyond the curl.

Drainage holes are located at approximately 2.0 cm intervals in a spiral configuration along the mainshaft of the stent.

The Circon-Surgitek Classic Double Pigtail Ureteral Stent is designed for endoscopic or open surgical placement. A medial line is imprinted along the mainshaft of the stent on the side opposite the proximal curl to assist the physician in correctly orienting the curls within the kidney and bladder. The medial line terminates at the axial ring, parallel to the center radius of the distal curl. The axial ring serves as a visual marker to the physician for placement of the stent. The physician advances the stent until the ring is adjacent to the ureterovesical junction. This allows a sufficient amount of the stent to remain in the bladder to fully form the distal curl.

A non-absorbable monofilament trailing suture is provided in the distal curl to assist the physician in stent placement and positioning. To protect the suture, a retaining tube is placed over the tapered end of the stent.

Note: THE SUTURE RETAINING TUBE MUST BE REMOVED PRIOR TO USE.

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Other currently marketed components to be packaged with the Circon-Surgitek Classic Double Pigtail Ureteral Stent include:

- One (1) Push Catheter

8. Summary of Safety and Effectiveness

Double-pigtail stents provide a safe and effective method of ensuring urinary drainage. Resnick described the use of Ureteral Stents “to provide urinary drainage when renal obstruction occurs secondary to a chronic process, such as malignancy, edema, and stricture or in obstructed patients, to maintain constant drainage through the course of the illness. Other uses include temporary insertion to relieve obstruction, usually in association with a ureteral stone, intra-operatively during renal procedures, such as pyeloplasty; or during ureteral procedures such as repair of ureteral injuries; or in association with urinary diversion.”¹

The Tecoflex material used to manufacture the device has been used in other commercially available stents that have been determined as substantially equivalent. The kidney curl strength, bladder curl strength, break strength and elongation of the Circon-Surgitek Double Pigtail Stent is similar to other commercially available double pigtail stents that have been determined as substantially equivalent.

¹ Resnick MI: A guide to double-pigtail stents, Contemp Urology, Oct. 1994, pp. 59-66.