

# Brief Summary Document

## Overview

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### Product

Clear Renal Sheath

IFU 51649590-01B

### Rx Statement

*CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner.*

*This device is restricted to use by or under the supervision of physicians trained in nephrostomy procedures.*

*Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.*

### Content

#### Intended Use/ Indications of Use

The Clear Renal Sheath is recommended for the establishment of percutaneous access.

#### Contraindications

- This product is contraindicated in the presence of conditions which create unacceptable risk during catheterization

#### Precautions

- A thorough understanding of the technical principles, clinical applications, and risks associated with percutaneous nephrostomy is necessary before using this product.
- Do not advance the Clear Renal Sheath if significant resistance is encountered. Forceful insertion may result in patient injury.
- The recommendations given are meant to serve only as a basic guide to the utilization of of this set. The performance of percutaneous nephrostomy should not be undertaken without comprehensive knowledge of the indications, techniques, and risks of the procedure.

#### Potential Adverse Events

Possible adverse events which may result from an access procedure include:

- Avulsion
- Bleeding
  - Hematoma
  - Hematuria
  - Hemorrhage
- Edema

- Extravasation
- Fistula
- Infection
- Injury to the kidney
- Laceration
- Obstruction
- Pain
- Renal Insufficiency/ Failure
- Tissue perforation
- Tissue trauma
- Unretrieved Device Fragments (UDF)

Adverse events may require additional medical or surgical intervention.

There are currently no known **WARNINGS** associated with the use of these devices.