

Brief Summary Document

Overview

Product

Amplatz Type Renal Sheath

IFU 51649587-01B

Rx Statement

CAUTION: Federal law (USA) 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 Amplatz Type 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 Amplatz Type 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 these products. The performance of percutaneous nephrostomy should not be undertaken without comprehensive knowledge of the indications, techniques, and risks of the procedure.

Potential Adverse Events

The adverse events which may result from an access procedure include but are not limited to:

- 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.