SurgyNeedle Instructions For Use

15-gauge (Item # 780-411), 18-gauge (Item # 780-413), 21-gauge (Item # 780-412) & 23-gauge (Item # 780-414, 780-415)

The following information should be read before using this device:

DEVICE DESCRIPTION:

U.S. Surgitech's SurgyNeedle is a single use aspiration needle designed with a beveled stainless-steel needle tip for the controlled penetration of cysts and organs. SurgyNeedle has a transparent 5mm shaft and a proximal Luer-Lock connection for the attachment of a standard syringe for fluid aspiration.

CONTRAINDICATIONS:

The instrument is not intended for use when minimally invasive techniques are contraindicated.

INSTRUCTIONS FOR USE:

1. Using sterile technique, remove the instrument from the packaging. To avoid damage, do not flip the instrument into the sterile field.
2. Inspect the needle tip prior to inserting it into the abdomen through a 5mm trocar.
3. Using appropriate technique, insert the needle tip into the cyst/organ to be drained.
4. Attach an appropriately sized syringe to the proximal Luer-Lock connector to aspirate or inject the desired volume of fluid.

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PRECAUTIONS/WARNINGS:

- These devices are designed for single use only and are not to be reused, reprocessed or re-sterilized. Do not use if packaged is opened or damaged.
- All procedures should be performed only by physicians with adequate training and knowledge of these procedures. In addition, medical literature should be consulted regarding techniques, hazards, contraindications and complications prior to the performance of these procedures.
- Before any instruments and accessories from different manufacturers are utilized together in a procedure, verify compatibility.
- Transport and store all products safely at ambient temperatures of 5°C to 30°C and relative humidity of 35% to 65 % (non-condensing). Handle with care.
- When removing from surgical site, inspect again to insure needle is intact.

SINGLE USE PRECAUTION:

These devices are designed and sold for single use only. Reprocessing and/or re-sterilization is not permitted. The effects of any unauthorized reprocessing and/or re-sterilization can result in the following complications:

- Cross-contamination due to ineffective reprocessing/re-sterilization.
- Mechanical fatigue, and associated failure due to the effects of reprocessing/ re-sterilization.

Note: SurgyNeedle is supplied sterile for single patient use only. Discard after use.