

Precio UroGuide®

Assistive Device for Safe and Precision Percutaneous Access

PUG®'s Features and Strengths:

- **Effective Systematic Precision**
Systematic adjustments with multiple degree of freedom and accurate aiming procedure to simplify 3D alignment of the needle with precision
- **Reduced Exposure to Radiation**
Needle being held by a compliant mechanism, allowing reliable remote adjustment by the surgeon from outside the X-ray burn-field
- **Intuitive + Touch and Feel**
Intuitive to use while retaining the touch & feel of the insertion for the surgeon, ensuring full confidence on the puncture while surgeons make all the calls
- **Fast yet Safe**
SOP that cuts short surgery time to in turn reduce X-ray radiation dosage and lower surgery cost
- **Flexibility**
Support both bi-plane and bull's eye techniques, providing surgeons with flexibility based on needs and preference
- **Shorter Learning Curve**
Cut short learning curve to allow surgeons to pick up and get familiar with this difficult-to-master skill readily
- **Non-Robotic: Low Cost + Efficient**
Non-robotic and passive, enabling easy and fast set up, reliable and safe to use, plus low per-surgery cost allowing its use in a broad spectrum of simple to complex and low to high value procedures

A New Standard for Precise Interventional Procedures

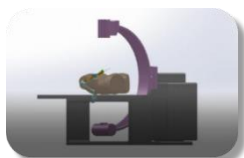
State-of-the-art medical technology and device is the key to modern minimally-invasive surgical procedures and biopsies, demanding solutions that are safe, precise and reliable. The National University Hospital, National University of Singapore and Institute of Technical Education, have hence joined hands to invent a Precio UroGuide® (PUG®), which is the world's first non-active Class I / Class A Sterile surgical device and procedure, for assisting surgeons in precision fluoroscopic, CT and ultrasound-based image-guided percutaneous accesses to stones, lesions and abscesses in deep organs such as kidney. PUG® can support many applications in intervention radiology and minimally-invasive surgeries, such as Percutaneous Nephrolithotomy (PCNL), as well as complex biopsies that require precision needle targeting and access.

Safe, Effective and Efficient Patented / FDA / CE Approved

PUG® is consisted of a compliant plastic needle holder/clamp unit intended for single use for each percutaneous access, and a reusable guidance controller that is ergonomically designed for the surgeons to remotely control the alignment of the needle external to the burn-field of the fluoroscope, ensuring safe, precise and accurate penetration.



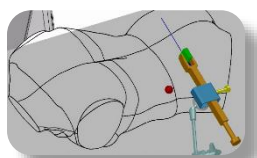
This device solves the problem of needle puncture during minimally-invasive surgery and biopsy, that were traditionally being performed by surgeons with no tool or device but only their hands exposing under radiation from imaging device such as a fluoroscope. This new device/technology makes possible remote, systematic and precision adjustment, accurate aiming and targeting of needle during percutaneous access procedure using either the bi-planar or the bull's eye technique, giving surgeons more options and control during the procedures.



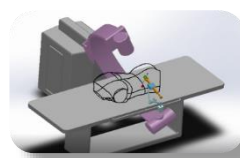
C-Arm Fluoroscopy Guided



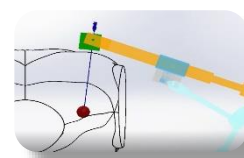
Step 1 – Quick Set Up



Step 2 – Establish Target Plane



Step 3 – Triangulation



Step 4 – Depth View & Align

Manufacturer Statement of Device

About the Device

Brand/Device Name:	Precio® UroGuide® (PUG®)
Device Classification:	Reusable: Class A / Class I, Single Use: Class A Sterile / Class I Sterile
Indications for Use:	Percutaneous Nephrolithotomy (PCNL)
Description:	Passive mechanical device to assist surgeon in achieving safer, faster, reduced radiation dosage, and a more effective PCNL needle puncture under fluoroscopy guidance with systematic and precision control and alignment of IP needle using the method of triangulation
Modules:	Reusable - Guidance Module (INV-01), Arm Clamp (INV-02) Single Use - Needle Holder (INV-03)

Regulatory Approval/Certificate

Certificates:	HSA - Dealer's License no.: ES0500326 (Class A Medical Device Registry) FDA - Establishment License no.: 3016880796 (Class I). Product Code: FHQ
----------------------	---

Technical Specifications

Principles:	Bi-planar Triangulation
Materials:	PEEK (01668 TECAPEEK MT natural), SSL (AISI 316L), PC (Makrolon 2458)
Sterilisation:	Sterrad®
Maintenance:	Preventive maintenance on every 50 uses / 6 months in service, whichever first
Warranty:	Full for first 100 uses / 12 months in service, whichever first (excl. fair wear & tear)
Expected Lifespan:	500 uses or 48 months in service, whichever first

Documentation

User's Manual:	PUG-IFU-001 (Instructions for Use)
-----------------------	------------------------------------

Manufacturer Information

Country of Origin:	Made in Singapore
Manufacturer:	Invivo Medical Pte. Ltd. (UEN: 201709849C)
Regulatory:	ISO 13485:2016 – SG18/81841646