PanPlasty® Instrument System

BEFORE USING PRODUCT, READ THE FOLLOWING IMPORTANT INFORMATION

INTRODUCTION

This Instruction For Use (IFU) manual is the most comprehensive source of information for the safe and effective use of the PanPlasty® System. This manual may be used by in-service trainers, physicians, nurses, surgical technologists, and biomedical equipment technicians.

The following conventions are used in this manual:

- A WARNING highlights a safety-related issue. ALWAYS comply with this information to prevent patient and/or healthcare staff injury.
- A CAUTION highlights a product reliability issue. ALWAYS comply with this information to prevent product damage.
- A NOTE supplements and/or clarifies procedural information.

DESCRIPTION

The PanPlasty® Instrument System is a cutting-edge, minimally invasive guide designed for the precise targeting of intraosseous lesions. Distinctively crafted for surgeons, this system boasts several unparalleled features. Firstly, it substantially reduces the need for inoperative imaging, with imaging being utilized primarily for confirmation – a departure from conventional methods. Secondly, it offers custom translation capabilities ensuring precise lesion localization. Lastly, it is versatile in its compatibility with biologics, provided they can flow seamlessly through the custom trocar. It's essential to note that every component of the PanPlasty® Instrument System is designed for single use, ensuring optimal performance and patient safety with every procedure.

Contraindications

- Infection
- Physiologically or psychologically inadequate patient
- Inadequate skin, bone, or neurovascular status
- Irreparable knee complex
- Possibility for conservative treatment
- Growing patients with open epiphyses
- Patients with high levels of activity

USER/PATIENT SAFETY

WARNINGS:

- Before using this instrument, read and understand the instructions. Pay particular attention to WARNING information.
- For use by qualified personnel trained in the use of surgical instruments and relevant surgical procedures.
- Modification or mishandling of the instruments will invalidate the functionality of the instruments and may result in improper function of the instruments.

MAINTAINING DEVICE EFFECTIVENESS

- The surgeon should have specific training, experience, and thorough familiarity with all aspects of this procedure.
- The PanPlasty® Instrument System can be used with any 3mm diameter access trocar like the 160mm PanOrthopaedics trocars RIN-11-196-CT or RIN-11-196-OT.
- Any noise or unusual sensation during trocar drilling should be reported to the surgeon.
- PanOrthopaedics recommends the use of the PanPlasty® Instrument System in a sterile environment.

HANDLING AND STERILIZATION

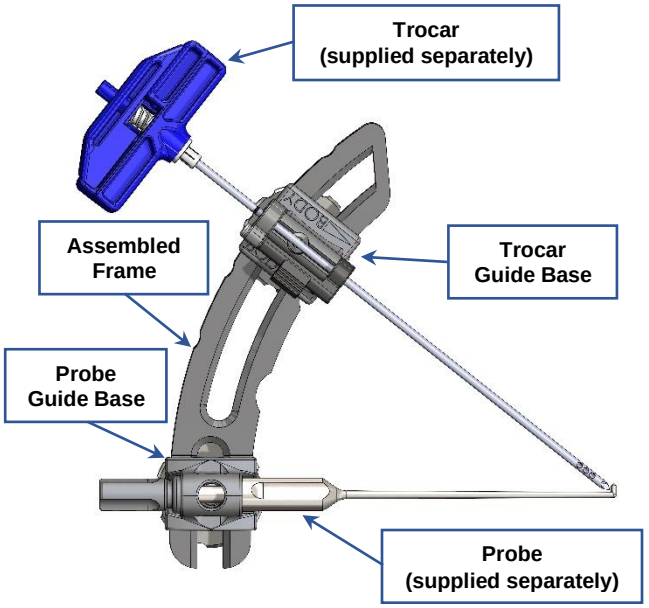
Sterile Products:

Trocar: The 160mm PanPlasty® trocars, RIN-11-196-CT and RIN-11-196-OT, are sterilized using ethylene oxide. They are provided **STERILE** for **SINGLE USE ONLY**. Do not re-sterilize. The risk of re-use of the devices includes potential for patient to develop infection. Do not use instruments after expiration date. Trocars should be intact upon receipt and opened using aseptic technique. After use, dispose of the trocar properly in a 'sharps' container. Please see trocar package insert and labeling for further information.

Frame/Probe: The PanPlasty® frames, 726-01-001 and 726-01-002 and the PanPlasty® probes, 726-01-030 and 726-01-031, are sterilized using electron beam. They are provided **STERILE** for **SINGLE USE ONLY**. Do not re-sterilize. The risk of re-use of the devices includes potential for patient to develop infection. Do not use instruments after expiration date. Frames/Probes should be intact upon receipt and opened using aseptic technique. The frame packaging is single sterile & double packaged. The probe packaging is single sterile & double packaged. After use, properly dispose of the frame and the probe. Please see frame or probe insert and labeling for further information.

INSTRUCTIONS FOR USE

Upon removal from packaging, inspect the instruments to ensure there is no damage. If damage is observed, discard the damaged instrument(s) and open a new single-use instrument kit.

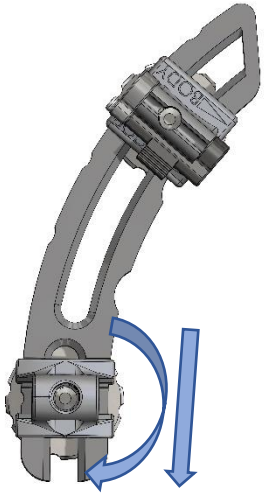


The Assembled Frame above is supplied and configured for RIGHT patient knees.

CONVERTING RIGHT TO A LEFT CONFIGURATION

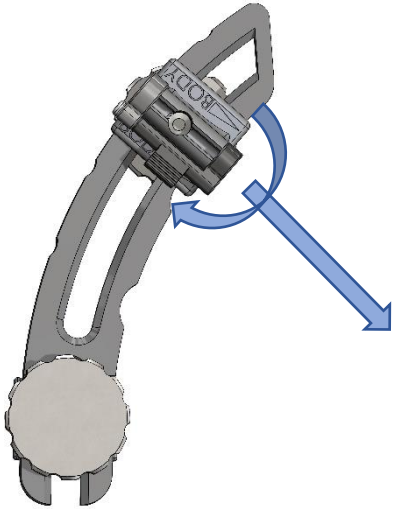
STEP 1:

Probe Guide Base: Loosen knob, remove assembly from open end and flip Probe Guide Base to the other side of the curved frame. Reinsert and tighten the knob into the Probe Guide Base.

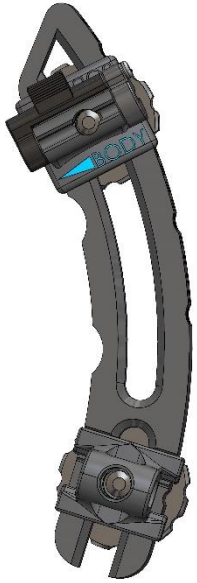


STEP 2:

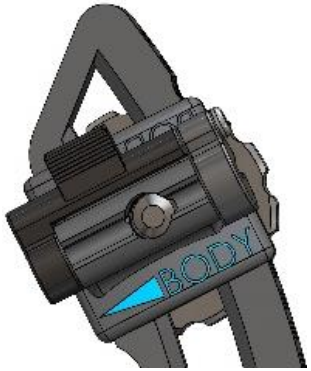
Trocar Guide Base: Loosen and remove knob, place Trocar Guide Base on other side of the frame matching the slot curvature. Reinsert, thread, and tighten knob into the Trocar Guide Base. **Ensure base is flat with frame surface.**



Frame configured for LEFT patient knee (below)



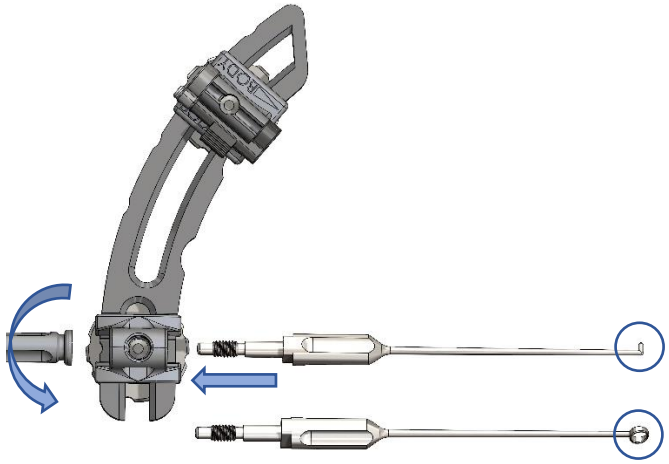
NOTE: To ensure correct assembly for left or right knee configuration, make sure that the word "BODY" (highlighted below) on the Trocar Guide Base is readable in the shown orientation and that the arrow points towards the patient. The direction of rotation of the swivel lock changes based on the left/right orientation.



PROBE INSERTION AND TRANSLATION ADJUSTMENT:

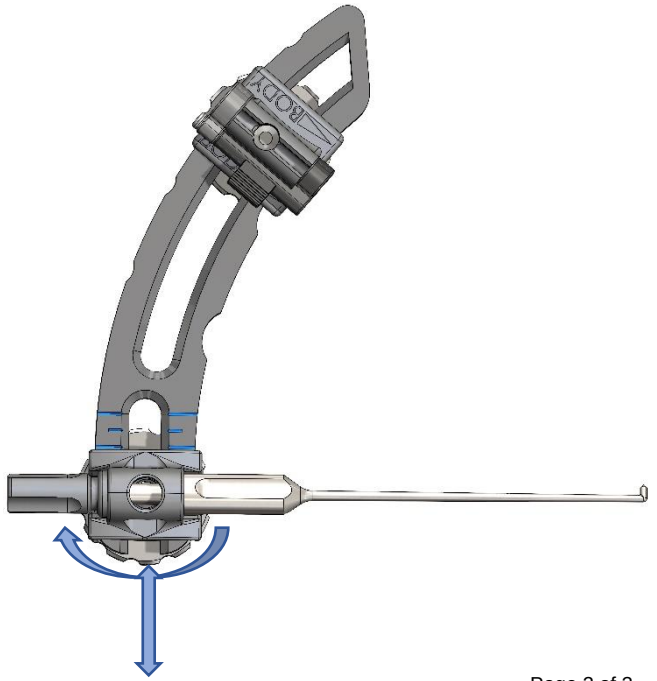
STEP 1:

Insert desired probe into Probe Guide Base and apply Probe Knob and tighten. NOTE: intended orientation of probe tips (ring or spike probes).



STEP 2:

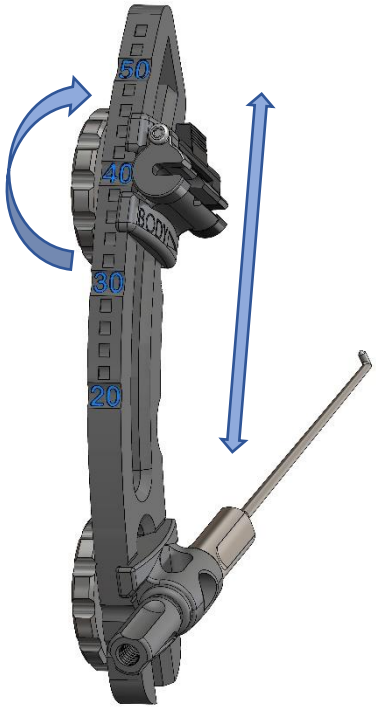
Loosen and tighten knob to desired degrees of translation (0 to 15 mm).



TROCAR DRILLING ANGULATION ADJUSTMENT

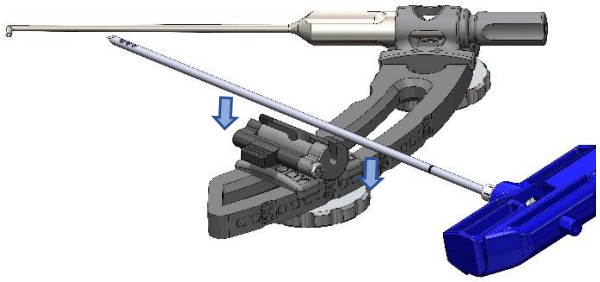
STEP 1:

Using numerical identification on the outside of frame, approximate angle (in degrees) with respect to probe tip.



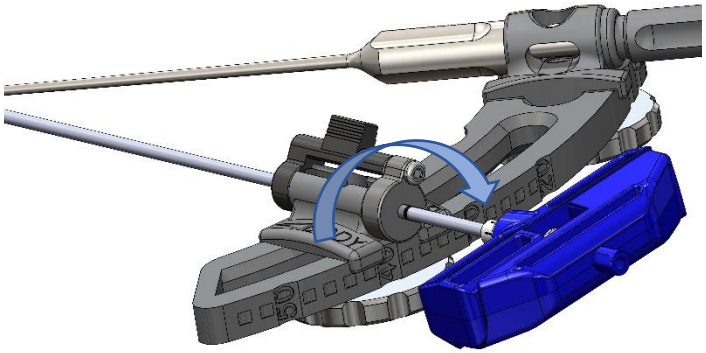
STEP 2:

Insert trocar into slot of Trocar Guide Base.



STEP 3:

Turn swivel lock to lock-in trocar into Trocar Guide Base. Reverse steps to detach Trocar from Trocar Guide Base/Frame intraoperatively.



STORAGE AND HANDLING

Devices should be handled with care at all times. Storage zones for surgical instruments should be away from areas of humidity and must be out of contact with UV rays and sources of electro-magnetic radiation.

CAUTION:

- The user should apply CAUTION when handling sharp instruments and instruments with pinch points such as bone reduction forceps.

SYMBOL	SYMBOL TITLE	SYMBOL DESCRIPTION
	General Warning Sign	Signifies a general warning.
℞ Only	Prescription Only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician.
	Manufacturer	Indicates the medical manufacturer.
	Date of Manufacture	Indicates the date when the medical device was manufactured.
	Use-By Date	Indicates the date after which the medical device is not to be used.
REF	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Do not use if package is damaged.	Indicates a medical device that should not be used if the package has been damaged or opened.
	Distributor	To indicate the entity distributing the medical device into the locale.
	Single Use	Indicates a medical device that should not ne resterilized.
STERILE R	Radiation Sterilization	Indicates a medical device sterilized by radiation.
	Single Sterile Barrier	Indicates a single sterile barrier system.
	Single Sterile Barrier System w/ protective packaging	Indicates a single sterile barrier system with a protective packaging outside.
	Consult Electronic Instructions For Use	Indicates the need for the user to consult the electronic instructions for use.

PRODUCT COMPLAINTS

The customer or health care provider should report any dissatisfaction with the product quality, product malfunction labeling, or performance to PanOrthopaedics immediately via telephone or email.

Manufactured by:
PanOrthopaedics®, Inc.
1776 Heritage Center Drive
Suit 204
Wake Forest, NC 27587
https://panorthopaedics.com
Telephone: 919-502-1320
E-mail: info@panorthopaedics.com