The Art of Precision

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

Treating intraosseous lesions is a minimally invasive fluoroscopically assisted procedure that targets and fills subchondral bone defects not intrinsic to the bony structure. These defects can be associated with bone marrow lesions (BML), insufficiency or microtrabecular fractures, repetitive stress injuries to the cancellous bone, or cysts. Successfully filling osseous defects of the trabecular bone requires an injectable material indicated for use. An optimal material for the procedure: 1. Flows readily into closed trabecular bone; 2. Provides physical consistency dependent on surgical goals with properties comparable to healthy cancellous bone, 3. If desired, undergoes cell-mediated remodeling as the bone heals.

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 trocar RIN-11-196-CT.
- 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.

MANUAL CLEANING AND STERILIZATION

Non-Sterile PanPlasty Instrument System:

Disassemble instruments prior to cleaning and sterilization. The use of the following, or equivalent, enzymatic detergents for this validated cleaning process.

Step 1	Prepare a neutral pH enzymatic cleaning solution per the instructions of the manufacturer.
Step 2	Immerse the instruments in the enzymatic solution and activate any moving mechanisms a minimum of five times.
Step 3	Soak the instruments in the enzymatic solution for a minimum of 15 minutes.
Step 4	While still in the soak solution, use a soft bristled brush to thoroughly scrub the instruments and remove all visible soil. Use appropriately sized cleaning brushes to thoroughly scrub all lumens. If at any time the detergent solution becomes grossly contaminated (bloody and/or turbid), prepare a fresh batch as described in the previous step.
Step 5	Remove the instruments from the enzymatic soak, rinse instruments thoroughly under running lukewarm tap water, taking care to flush all lumens or crevices, for at least one minute.
Step 6	Immerse the instruments in fresh enzymatic solution and sonicate for a minimum of 10 minutes.
Step 7	Rinse the instruments in deionized water. Ensure all hard-to-reach areas are flushed and continue rinsing until water runoff is free of suds.
Step 8	Dry the instruments with a sterile gauze pad, clean towel, and filtered pressurized air (< 40 psi).
Step 9	Perform a visual inspection on the instruments and verify that they are clean. If instruments are not visibly clean, repeat the cleaning procedure.

STERILIZATION

Unless specifically labeled sterile, the instruments are supplied NONSTERILE and MUST be sterilized prior to use. Remove all protective packaging and labeling and verify that all instruments are in their open and unlocked position within the instrument tray. sterilize using steam autoclave. The use of an FDA cleared sterilization wrap is recommended. Sterilize using the following recommended validated steam autoclave cycle:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-vacuum	270°F (132°C)	4 Minutes	30 Minutes

POINT OF USE REPROCESSING- PanPlasty Instrument System

Immediately after the surgical procedure, remove as much debris as possible from each instrument using a water moistened gauze pad, exchanging the gauze pad if it becomes soiled. Instruments should be soaked immediately after use; soiled instruments must be kept moist to prevent soil from drying. If the instruments cannot be soaked immediately, wrap them in a moist towel to prevent desiccation.

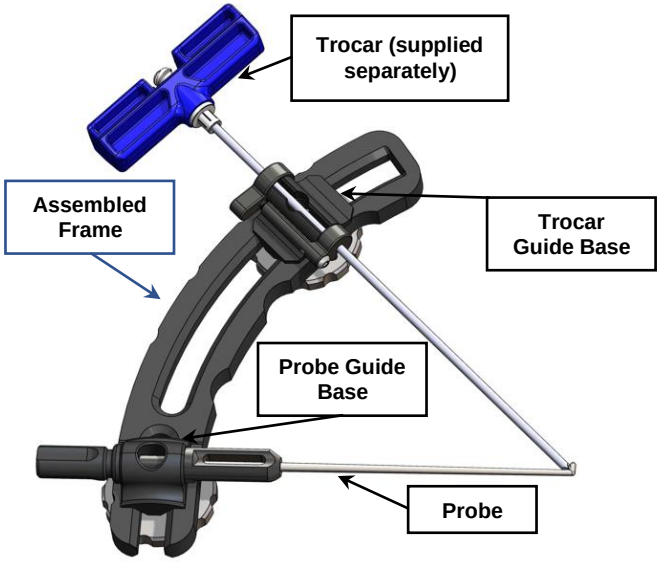
HANDLING AND STERILIZATION

Sterile Product:

Trocar: The 160mm PanPlasty trocar RIN-11-196-CT is sterilized using ethylene oxide. Do not re-sterilize. SINGLE USE ONLY. The risk of re-use of the device 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.

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.

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.

Frame configured for LEFT patient knee (below)

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).

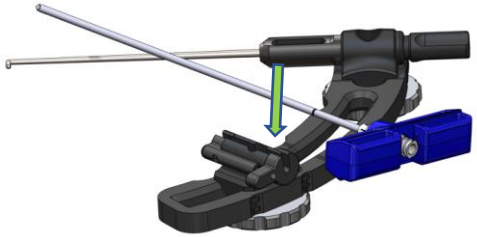
TROCAR DRILLING ANGULATION ADJUSTMENT

STEP 1:

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

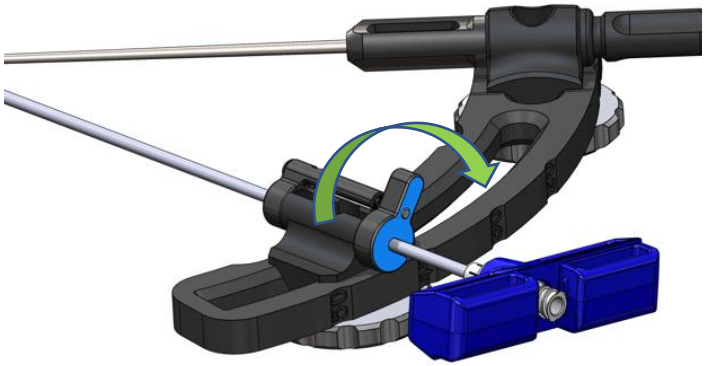
STEP 2:

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.
	Consult Instructions For Use	Indicates the need for the user to consult the 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 and Distributed by:
PanOrthopaedics
1776 Heritage Center Drive
Suit 204
Wake Forest, NC 27587
https://panorthopaedics.com
Telephone: 919-502-1320
E-mail: info@panorthopaedics.com