Instruction Full Sheet Specification

Part Number	Revision	Description	UOM
NW0767	E	IFU, 6988A-GT-ACP PROAXIS PKIT	EA

Purchasing Information

Manufacturer	Mfg. P/N
ANY	NW0767

Description (critical information, e.g. size, material, tolerance or other parameters; font, margin, paper type, etc.)

- Size = 8.5 x 11
- Standard 20 lb. white copy paper, or equivalent
- Margins (minimum) = Top: .25", Bottom: .25", Left: .5", Right: .5"
- Template must include:

  Standard Header:
  Approved Mizuho OSI logo graphic = .34" x 1.55" or larger

  Top, Page 1:
  Device Description = 12 -14 pt. Arial bold, all capitals
  Ref (Part Number) and Quantity = 12 - 20 pt. Arial
  Standard disclaimer e.g. for Single Patient Use Only = 10 -14 pt. Arial, bold

  Bottom, Page 1:
  Designated area for Symbols

  Date of Manufacture: Locate above line next to 

  Mizuho OSI Name = 10 - 12 pt. Arial, bold
  Address, telephone number, fax number and web address = 7 pt. Arial, bold
  European Representative name and address = 6 pt. Arial

  Standard Footer:
  Instruction Sheet Part Number, Revision, Title and CO Date = 6 -10 pt. Arial
- Print Type = black and white

Special Instructions (special handling requirements, refrigeration, exposure to sunlight, packaging etc.)

Note: Pages 1-2 are instructions and revision history only. Not to be included with the final printed instruction sheet shown on the following page(s).

Packaging Instructions: Bulk pack; label contents (not applicable when printed in house)

Inspection Criteria (consult with QA)

- Template shown is representative of actual Instruction Sheet. Layout and placement may differ as content is populated.
- Verify no blurring, ghosting, etc.
- Verify all pages are present.

Revision History

ECN	Rev.	Reason for Change	Effective Date
101506	A	Production Release	04/28/2014
102340	B	Delete DOM symbol; updated template and logo	06/24/2015
103389	C	Update names and symbols to current format as applicable. Remove patent number (does not apply to this kit). Update instruction sheet template to current revision.	06/14/2017
105828	D	Added MD medical device symbol and EU/ MDR language around reportability of a serious incident; General format changes, update non-product related wording to provide consistency with similar documents.	05/06/2021
2024	E	Updated EC REP address on page 1, added UKCA symbol and UKRP address to footer of page 1; update to current IFU template.	

ProAxis® SYSTEM
PATIENT CARE KIT INSTRUCTIONS FOR USE

REF 6988A-GT-ACP CONT 6

⚠ **CAUTION*:*** This Patient Care Kit is for **SINGLE PATIENT USE ONLY**. Discard after use.
Re-use of any component in this Patient Care Kit may result in cross contamination.

1. Open the Patient Care Kit. When using the GentleTouch® Prone Pillow, it is recommended to open the packaging at least 20 Minutes prior to use to allow for complete expansion of the Cushion. Follow the instructions on the underside of the GentleTouch® Prone Pillow for proper Cushion placement and additional warnings

   ⚠ **CAUTION:** When placing the patient on the ProAxis®, check to ensure the GentleTouch® Prone Pillow does not contact the Head-End Support Assembly or the Chest Pad during the anticipated patient range of motions. Monitor patient during table movement to ensure the desired head support is maintained.

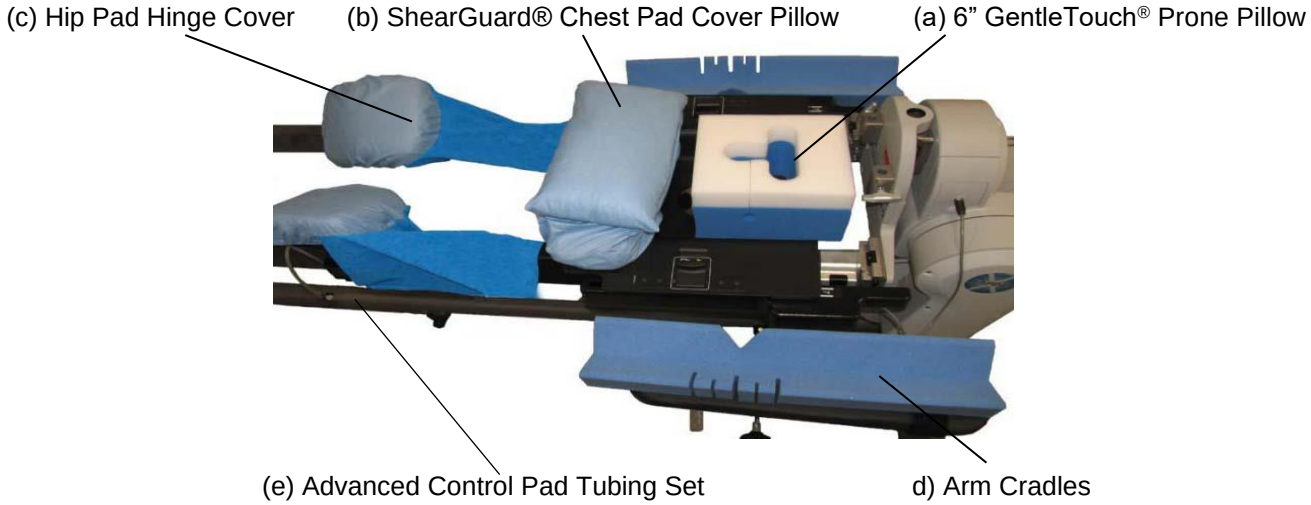
2. When applying the GentleTouch® Prone Pillow to the patient, place the white foam against the patient's face, and the blue foam on the table. Center the pillow opening over the patient and ensure the eyes are free from any pressure.
3. Connect the Advanced Control Pad Tubing to the connection port on the Foot-End column of ProAxis® and to the Hip Pads.
4. Apply the Single Chest Pad Cover.
5. Apply the Hip Pad Covers over the Hip Pads by covering the distal end of the pad and pulling toward the Chest Pad. Extend the elastic portion of the Hip Pad Cover over the ProAxis® hinge and secure with the Velcro® strips. Confirm the contact surface of the covers are smooth and without wrinkles or folds. Confirm that the Hinge Cover does not impede the movement of the Torso Trolley®. Re-adjust the portion covering the hinge as needed.
6. Once the patient has been transferred, gently lift the patient at the location of contact for each pad and smooth the contact surface of the cover.

   ⚠ **CAUTION:** Confirm that the patient is free of any skin folds and is absent of any pressure on the nipples. Re-check the patient at all contact points throughout the procedure to ensure proper positioning.

7. Place the Arm Cradles between the Arm Boards and the patient.

PKIT 6988A-GT-ACP *includes:*

a) 1-6" GentleTouch® Prone Pillow
b) 1-ShearGuard® Chest Pad Cover Pillow
c) 2-Hip Pad Hinge Covers
d) 2- Arm Cradles
e) 1 Advanced Control Pad Tubing Set



NOTE: *(European Union) Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.*

www.mizuhosi.com/resources/symbols

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