

Instructions For Use

MORPHBOARD®

LongBoard

SINGLE-PIECE PEGBOARD



PegDok™
PEGBOARD PEG STABILIZER

TUFFease®
GEL SURGICAL PADS

Catalog Number **105-LB**

Doc Title **IFU-IMP-0048**

Revision **00**



Intended Use/Intended Users: The MorphBoard is a medical device used in orthopedic surgery to assist with the positioning of a patient's hip during procedures such as hip replacement (partial and total hip replacement). Orthopedic surgeons are the intended users.

Target Patient Group: The target patient group typically includes individuals who require hip surgery for various reasons such as hip replacement. Patient selection depends on the judgment of the surgeon. Surgeon must consider health and size of the patient. There is no weight requirement for the positioner, but each position has a maximum range.

Contraindications:

- Severe medical instability: Patients who are medically unstable may not be suitable candidates for hip surgery, and consequently, the use of a MorphBoard should be avoided.
- Allergies or skin conditions: Patients with known allergies to materials used in the MorphBoard or those with skin conditions that could be exacerbated by contact with the device may not be appropriate candidates.
- Infection: In the presence of an active or uncontrolled infection in the surgical area, the use of a MorphBoard may be contraindicated as it could increase the risk of complications.
- Fractures or bone disorders: Certain bone conditions or fractures may make the use of a MorphBoard challenging or unsafe.
- Vascular conditions: Patients with severe vascular conditions that affect blood flow to the lower limbs may not be suitable candidates, as the use of a hip positioner peg board could exacerbate circulation problems.

Warnings/Precautions

- Do not use device in a manner that doesn't follow these instructions for use.
- The surgical team, including the surgeon, nurses, and anesthesia providers, should be adequately trained in the use of the MorphBoard to ensure safe and effective patient positioning.
- Follow the IFU to correctly set up the product.
- Pressure Sores: Prolonged pressure on the patient's skin, especially in areas in contact with the peg board, can lead to pressure sores. Regular monitoring and repositioning of the patient are essential to prevent this complication. Always use IMP patient protective peg pads.
- Patient Positioning: Ensuring that the patient is correctly positioned on the peg board is critical. Misalignment or improper positioning can result in suboptimal surgical outcomes or complications.
- Device Maintenance: Regularly inspect and maintain the hip positioning peg board to ensure it is in good working condition. Damaged or worn-out components should be replaced promptly.

Risks:

- Peg may dislocate.
- Plastic of MorphBoard could elongate to the point that the pegs may not seat well.
- Locking pegs may lose function when dropped.

Complaints and Adverse Events: For complaints and adverse events, contact IMP and the appropriate regulatory authorities for specific country.



Innovative Medical Products
87 Spring Lane
Plainville, CT 06062
USA
P: 860-793-0391
F: 866-459-1805
info@IMPmedical.com



BEO MedConsulting Berlin GmbH
Helmholtzstraße. 2-9
10587 Berlin
Germany
Telephone +49 (0)30 318 045 30
Fax +49 (0)30 318 045 40
Email info@beoberlin.de



Product Identification

Part No	Product Name	GTIN
105-LB	MorphBoard® LongBoard	00696588007960

Consumables:

- Patient Protective Peg Pad
- MorphBoard Foam Baseplate Pad

Disposal of unit:

If a device is being returned for repair or disposal, please contact Innovative Medical Products at sales@IMPmedical.com. If the device is not being returned, instruments are to be disposed of in accordance with applicable laws, rules, and regulations for the disposal of biohazardous waste. Follow all guidelines for biohazardous waste in accordance with the Centers for Disease Control and Prevention guidelines as well as applicable federal/national, state and local regulations.

Acceptable Accessories:

Part No	Product Name	GTIN
105-PD-2	PegDok™ 2 Hole	00696588007755
105-PD-1	PegDok™ 1 Hole	00696588007748
105-8	8" Aluminum Peg for MorphBoard®	00696588002101
105-9	9" Aluminum Peg for MorphBoard®	00696588002118
105-12	12" Aluminum Peg for MorphBoard®	00696588002125
105-14	14" Aluminum Peg for MorphBoard®	00696588002132
105-8 CP	8" Composite Peg for use with MorphBoard®	00696588002149
105-9 CP	9" Composite Peg for use with MorphBoard®	00696588002156
105-12 CP	12" Composite Peg for use with the MorphBoard®	00696588002163
105-14 CP	14" Composite Peg for use with the MorphBoard®	00696588002170
105-8P	8" Patient Protective Peg Pad	00696588002354
105-9P	9" Patient Protective Peg Pad	00696588002378
105-12P	12" Patient Protective Peg Pad	00696588002392
105-14P	14" Patient Protective Peg Pad	00696588002415
TE-MBP	TUFFease® Gel Pad 50" x 20" x 1/2" for MorphBoard®	00696588003009
TE-LXP	TUFFease® Leg Extension Gel Pad 36" x 12" x 1/2"	00696588002996
105-PD-S	PegDok™ Small	00696588007762
105-LB-EXT	MorphBoard® LongBoard Leg Extension	00696588007984
105-BP-G	MorphBoard® Foam Baseplate Pad (10/case)	00696588002064
105-LB-EXT-HP	MorphBoard® LongBoard Leg Extension Hinge Pin	00696588008004

Symbol Glossary

Symbol	Title	Description	Standard
EU REP	Authorized Representative in the European Community	Indicates the authorized representative in the European Community.	ISO 15223-1:2021
LOT	Batch Number	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2021
REF	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be	ISO 15223-1:2021



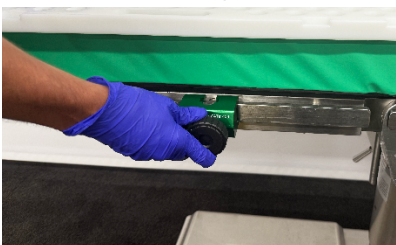
Symbol	Title	Description	Standard
	Authorized Representative in the European Community	Indicates the authorized representative in the European Community.	ISO 15223-1:2021
		identified. The manufacturer's catalog number shall be placed after or below the symbol and adjacent to it.	
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot be presented on the medical device itself.	ISO 15223-1:2021
	Complies with European Directives.		
	Consult instructions for use		ISO 15223-1:2021
	Date of manufacture	The date must be presented in the following format: YYYY-MM-DD	FDA 21 CFR 801
	Keep Dry		ISO 15223-1:2021
	Manufacturer	This symbol shall be accompanied by the name and address of the manufacturer.	ISO 15223-1:2021
	Medical device		ISO 15223-1:2021
	Not made with natural rubber latex		Manufacturer defined
	Unique device identifier		ISO 15223-1:2021

**Instructions for Use MorphBoard LongBoard (CAT #105-LB):**

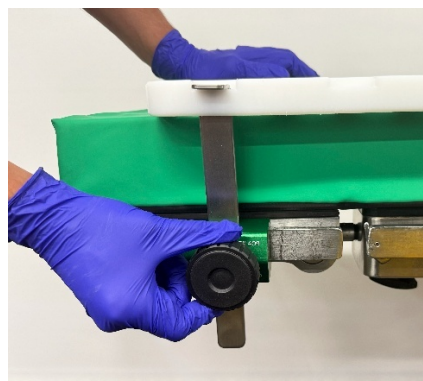
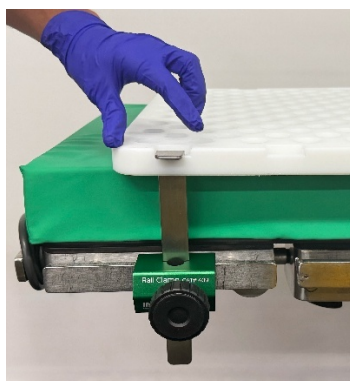
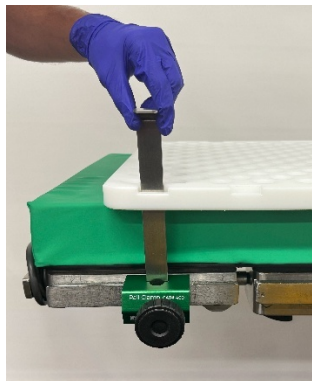
1. Position the LongBoard on the OR table.



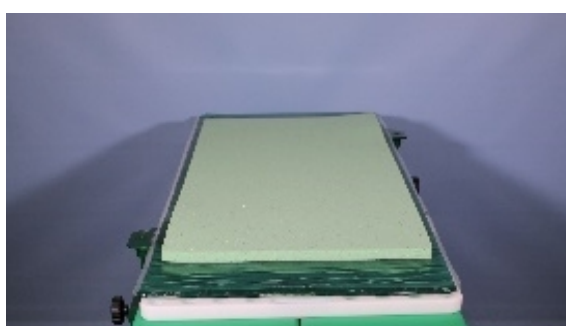
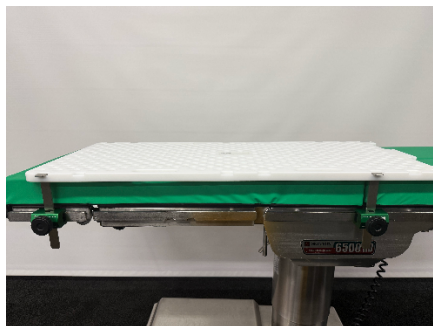
2. Slide two IMP Rail Clamps onto the same side of the OR table. Place the clamps underneath 2 inlets on the LongBoard.



3. Once both clamps are positioned underneath 2 separate inlets on the LongBoard, put the Drop Bar (325-DB) through the inlet and through the clamp. Once the Drop Bar is slid fully into the LongBoard & Rail Clamp, tighten the knob on the Rail Clamp. Do this for both Clamps.

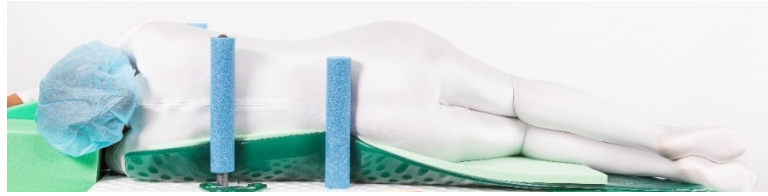
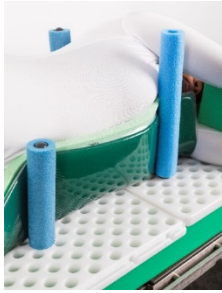


4. Place the protective pads on the LongBoard.



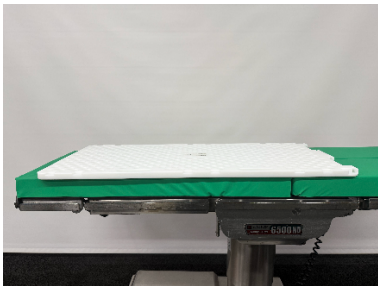


- Place the patient in the lateral position on the protective pad. Place foam covers on pegs and insert covered pegs into the board based on surgeon preference:

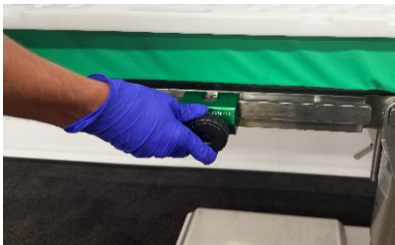


Instructions for Use Leg Extension CAT #105-LB-EXT:

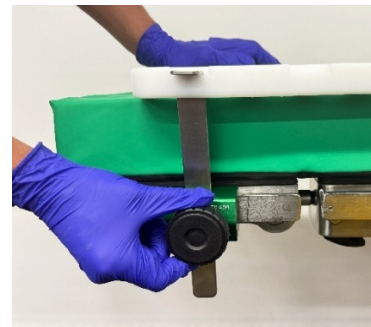
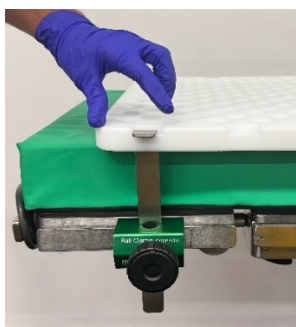
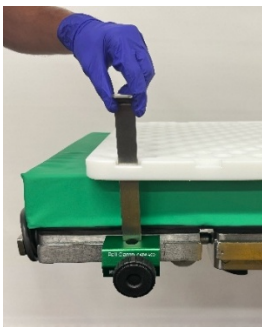
- Position the LongBoard on the OR table.



- Slide two IMP Rail Clamps onto the same side of the OR table. Place the clamps underneath 2 inlets on the LongBoard.



- Once both clamps are positioned underneath 2 separate inlets on the LongBoard, put the Drop Bar (325-DB) through the inlet and through the clamp. Once the Drop Bar is slid fully into the LongBoard & Rail Clamp, tighten the knob on the Rail Clamp. Do this for both Clamps.





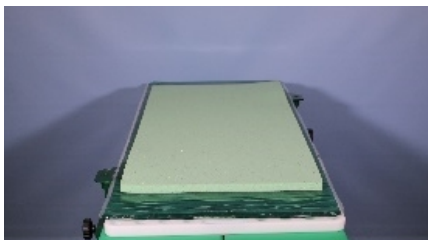
5. Retrieve the Leg Extension Board and align it on either side of the MorphBoard Longboard. Once aligned, push the Hinge Pin through both the LongBoard and the Leg Extension.



6. Lower the kickstand of the Leg Extension by disengaging the first pin. Once the kickstand is at 90°, the height of the kickstand can be adjusted by moving the second pin.



7. Place patient protective pads onto the boards.





8. Position the patient in the lateral position. Place pegs into protective single-use foam covers.



9. Lower end of the OR table to provide an anterior dislocation of the hip, positioning the leg posteriorly.



Instructions for Use PegDok:

105-PD-S Set up

Option 1:

1. Place the PegDok into the MorphBoard in the location where the patient should be supported

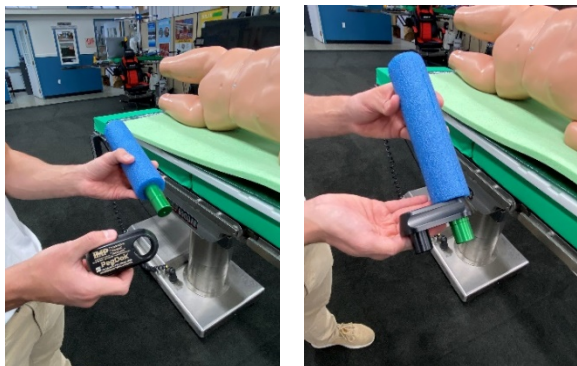


2. Place the covered peg into the PegDok and fully push into the MorphBoard



**Option 2:**

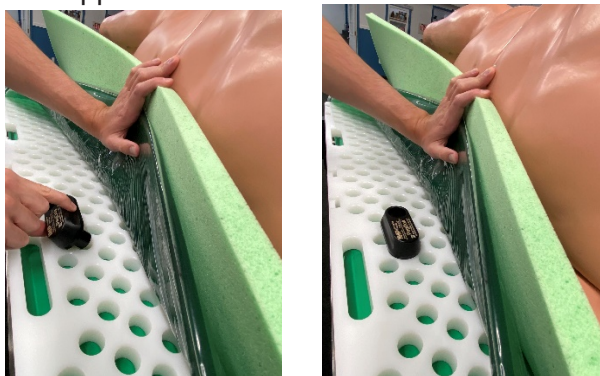
1. Place the covered peg into the PegDok



2. Insert the PegDok and covered peg into the MorphBoard where the patient should be supported and fully set it in place

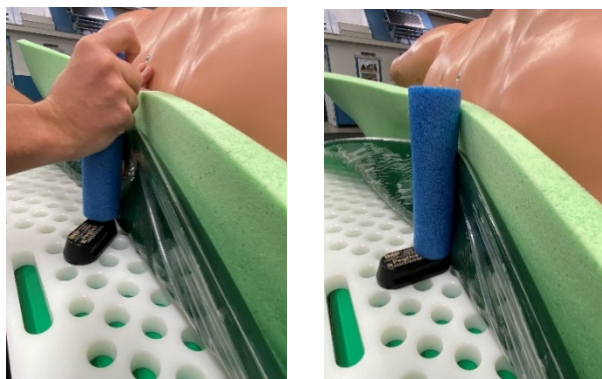
**Option 3:**

1. Place the PegDok into the MorphBoard in the location where the patient should be supported
2. Place the covered peg into the PegDok but do not fully set into MorphBoard





3. Rotate the peg into the final position and fully set into the MorphBoard



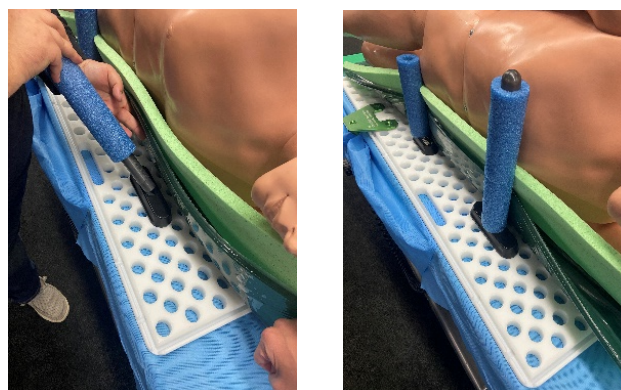
105-PD-1 Set Up

Option 1:

1. Place the PegDok into the MorphBoard in the location where the patient should be supported



2. Place the covered peg into the PegDok and fully push into the MorphBoard

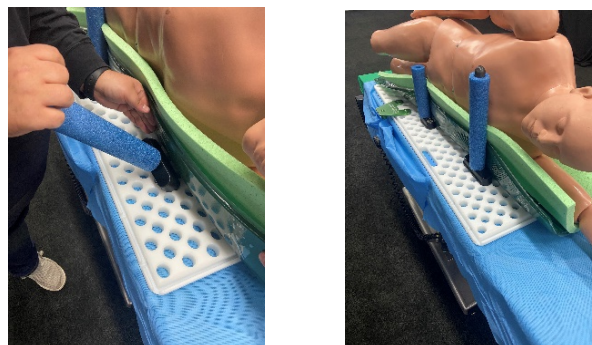


Option 2:

1. Place the covered peg into the PegDok



2. Insert the PegDok and covered peg into the MorphBoard where the patient should be supported and fully set it in place





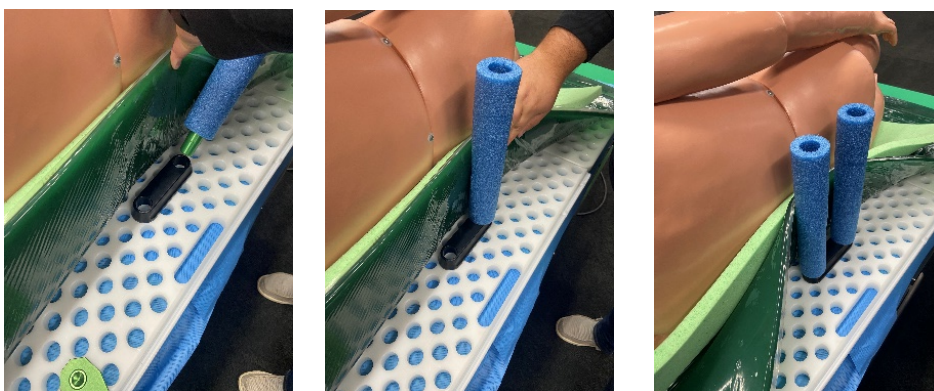
105-PD-2 Set Up

Option 1:

1. Place the PegDok into the MorphBoard in the location where the patient should be supported



2. Place the covered peg into the PegDok and fully push into the MorphBoard

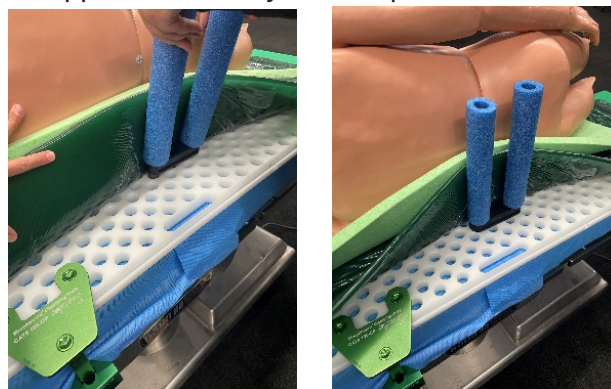


Option 2:

1. Place the covered pegs into the PegDok



2. Insert the PegDok and covered pegs into the MorphBoard where the patient should be supported and fully set it in place





Hand Cleaning Instructions

Recommended Instructions:

The Family of IMP Hip Positioners and all the positioner's components can be cleaned in the following manner:

1. Components may be disinfected, as a rule with any hospital grade disinfectant to reprocess the components between cases.

These include but are not limited to:

HI-TOR PLUS

BEAUCOUP GERMICIDAL DETERGENT

SANI MASTER II OR III

STARLINE INSTRUMENT DETERGENT.

2. A solution of water and liquid bleach (10 parts water to 1 part bleach) may also be used to clean and disinfect.

Thoroughly clean the components with your disinfectant. A final wipe down with clean water is recommended to be sure that no residue from the disinfectant is left on the components.

Completely dry the components and return them to the storage case to protect them from damage.

3. IMP recommends that all components for each system be kept together as a kit and a component not be used with another kit.
4. All components are tested as a kit before shipping.

TUFFease®

GENERAL PRODUCT USE

TUFFease Gel Pressure Reducing Pads are intended to minimize skin shear and increase pressure redistribution.

HANDLING

Always handle Innovative Medical Product TUFFease pads carefully. Never tear them away from table or other surgical equipment. Large table pads should be rolled and cradled when carried. Carts can be useful for larger pads and positioners. Carrying the gel unsupported can stretch the outer skin and cause undue stress that may result in splitting. Lifting the product from the corners may stretch the outer skin, causing stretch marks or tears.

CAUTION

Always avoid sharp objects and edges. **Never use alcohol to clean pads.**

HEATING AND COOLING

TUFFease pads show a high thermal capacity. In case of longer lasting operating procedures, the patient should be placed on pre-warmed pads in order to minimize patient heat loss. TUFFease® pads can be pre-warmed in a blanket warming cabinet, in hot water, or used in conjunction with either a hyper/hypothermia unit. Pads should not be warmed to temperatures above body temperature.



ELECTROSURGERY

TUFFease pads are non-conductive. If using HF surgical procedures, the patient must **NOT** be grounded to the earth. Otherwise, serious injuries (e.g., burns) may occur. Consult the high frequency expert of the operating department and the Electrical User's Guide for further instruction.

X-RAY

TUFFease® pads are x-ray radiolucent.

STORAGE

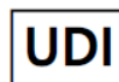
Pads should be stored in a dry area, in a flat or tightly rolled position on the cardboard roll supplied with the pad. Keep pads out of direct sunlight. Keep cabinet doors and other sharp objects from coming into contact with pad surfaces at all times.

CLEANING AND DISINFECTING

For cleaning and disinfecting always use conventional hospital approved topical equipment cleaner and disinfectants that **do not contain alcohol**. Pads are washable at temperatures of approximately 103°F/40°C. Make sure pads do not enter washing machines or dryers. Avoid alcohol and other strong, undiluted disinfectants. These may cause staining or hardening of the pad's outer skin. Thoroughly rinse products with clear water to remove any residue from cleaning solutions. **DO NOT AUTOCLAVE.**



Innovative Medical Products
87 Spring Lane
Plainville, CT 06062
USA
P: 860-793-0391
F: 866-459-1805
info@IMPmedical.com



(01) 0 0696588 00124 1
(11) 250917
(10) 1234

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