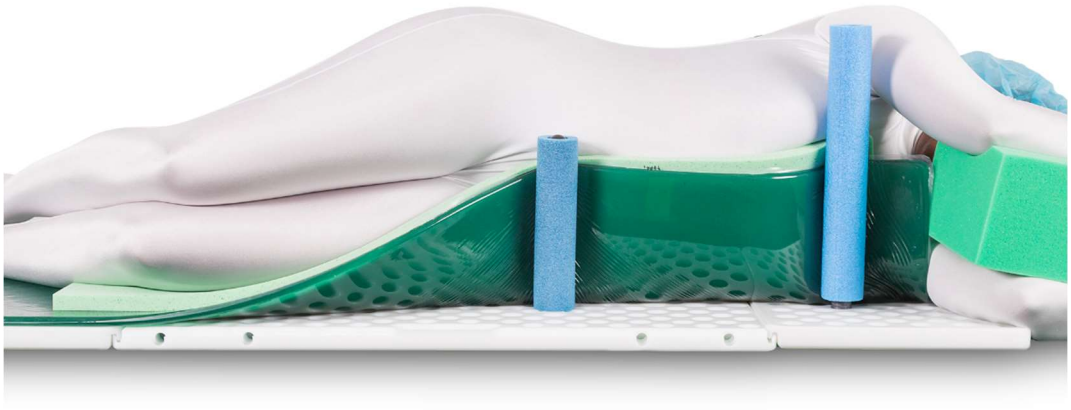
Positioned to Perform | Innovative Medical Products™

Instructions For Use

MorphBoard®

SURGICAL PEG BOARD



TUFFease®

GEL SURGICAL PADS

Catalog Number **105**

Doc Title **IFU-IMP-0019**

Version **2**

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.
- Incorrect set up – follow IFU.
- 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. Aways 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 loose function when dropped.

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

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Product Identification

Part No	Product Name	GTIN
105	MorphBoard®	00696588001234

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
105-8	8" Aluminum Peg for MorphBoard®	00696588002101
105-8 CP	8" Composite Peg for use with MorphBoard®	00696588002149
105-EP-8	8" De Mayo Expand-A-Peg® Locking Peg	00696588001654
105-9	9" Aluminum Peg for MorphBoard®	00696588002118
105-9 CP	9" Composite Peg for use with MorphBoard®	00696588002156
105-EP-9	9" De Mayo Expand-A-Peg® Locking Peg	00696588001661
105-12	12" Aluminum Peg for MorphBoard®	00696588002125
105-12 CP	12" Composite Peg for use with the MorphBoard®	00696588002163
105-EP-12	12" De Mayo Expand-A-Peg® Locking Peg	00696588001678
105-14	14" Aluminum Peg for MorphBoard®	00696588002132
105-14 CP	14" Composite Peg for use with the MorphBoard®	00696588002170
105-EP-14	14" De Mayo Expand-A-Peg® Locking Peg	00696588001685
TE-LXP	TUFFease® Leg Extension Gel Pad 36" x 12" x 1/2"	00696588002996
TE-MBP	TUFFease® Gel Pad 50" x 20" x 1/2" for MorphBoard®	00696588003009

Symbol Glossary

Symbol	Title	Description	Standard
EC REP	Authorized Representative in the European Community	Indicates the authorized representative in the European Community.	ISO 15223-1:2016
LOT	Batch Number	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2016
REF	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified. The manufacturer's catalog number shall be placed after or below the symbol and adjacent to it.	ISO 15223-1:2016

Symbol	Title	Description	Standard
	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 15223-1:2016
CE	Complies with European Directives.		
	Consult instructions for use		ISO 15223-1:2016
	Date of manufacture	The date must be presented in the following format: YYYY-MM-DD	FDA 21 CFR 801
	Keep Dry		ISO 15223-1:2016
	Manufacturer	This symbol shall be accompanied by the name and address of the manufacturer.	ISO 15223-1:2016
MD	Medical device		ISO 15223-1:2016
LATEX	Not made with natural rubber latex		Manufacturer defined
SN	Serial Number	The manufacturer's serial number shall be placed after or below the symbol and adjacent to it.	ISO 15223-1:2016
UDI	Unique device identifier		ISO 15223-1:2016

Instructions for Use:

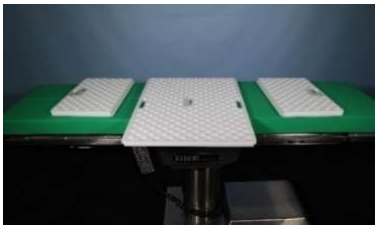
If Standard Set Up

1. Place the 3 Boards onto the surgical table making sure to interlock the 2 End Boards with the Center Board.



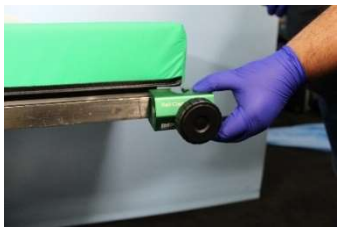
If Bariatric Set Up

2. Place the 3 Boards onto the surgical table to form a “T”, rotating the Center Board with the 2 End Boards making sure to interlock the 2 End Boards with the Center Board.



Continue Set Up

3. Slide the 2 rail clamps onto the surgical table rail based on surgical preference and position each clamp where the boards interlock.



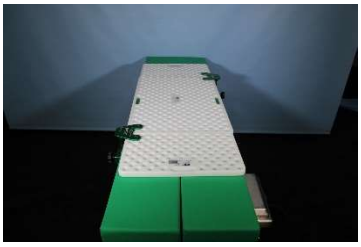
4. Slide the vertical bars of the clamping plates into the side rail clamps, bridging the interlocking grooves of the End Boards with the Center Board.

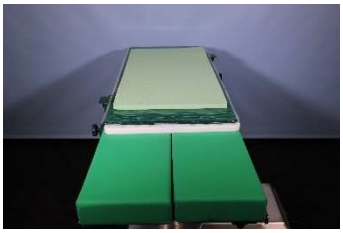
   It is important that the clamping plates span across the interlocking grooves.



5. Tighten the slide rail clamps to lock each clamping plate.

6. Place the Patient Protective Pad(s) onto the boards.



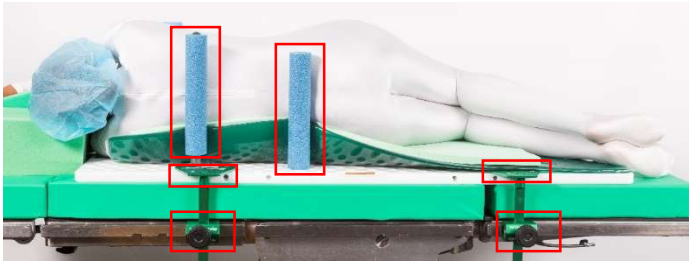


For patient's safety, always use IMP® Patient Protective Pads.

7. 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:


Safety Test

1. Check that all knobs are tight
2. Make sure that the clamping plates spans across the interlocking grooves
3. Make sure all pegs are covered with IMP Patient Protective Pads®

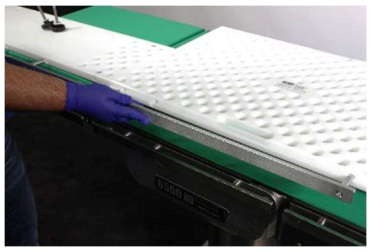


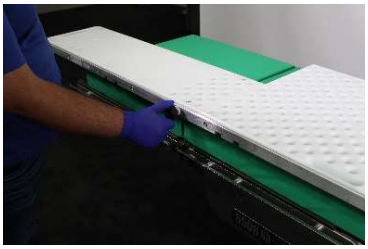
Instructions for Use Leg Extension:

1. Position Center Board 1 inch from the end of the center section of the OR table. Position Leg Extension Board on the opposite side of the table than the operative leg and interlock Leg Extension Board onto the Center Board

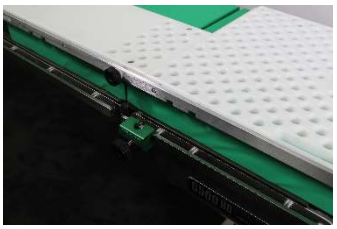


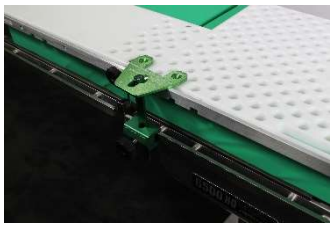
2. Attach the MorphBoard side rail to the Center Board and Leg Extension Board utilizing 2 black threaded knobs.





3. Slide the Rail Clamp onto the OR table rail and position it at the interlocking section between the Center Board and the Leg Extention Board. Once positioned, insert the MorphBoard Adjustable Clamping Plate (CAT# 805) into the Rail Clamp and secure to the boards, bridging the interlocking grooves of the Center Board and the Leg Extention Board.





4. On the opposite side, slide two Rail Clamps onto the OR table rail. Insert a MorphBoard Clamping Plate (CAT# 105-CP) into each Rail Clamp and lock into the Center Board.

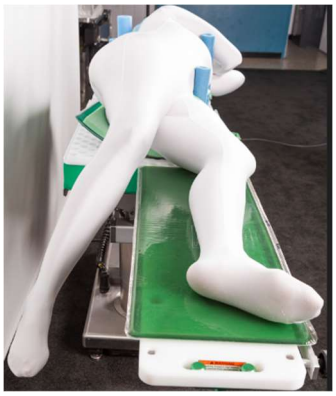
5. Position the Spring-Loaded Support Stand into cutout of the extension board. Loosen lever and retighten when raising or lowering OR table.

CAUTION: When adjusting the Spring-Loaded Support Stand, please note that this part has a spring-loaded mechanism. Extreme caution should be used when using this device.

6. Place patient protective pads onto the boards.


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

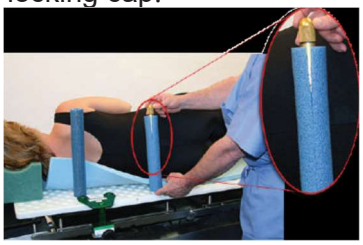
8. Lower end of the OR table to provide an anterior dislocation of the hip, positioning the leg posteriorly.



Instructions for Use Expand-A-Peg:

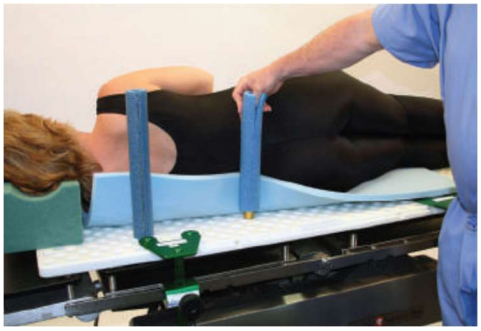
1. Place foam and pressure reducing pad on MorphBoard.

2. Slide IMP Patient Protective Pad over the Peg with the perforation away from the patient. Separate the perforation enough to access the locking cap.

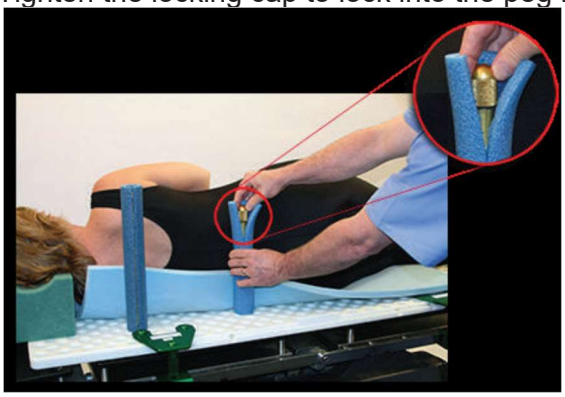


3. With the Expand-A-Peg Locking Peg in a “loose” position, insert the peg at an angle, locating the closest hole to the patient and securely place the peg.

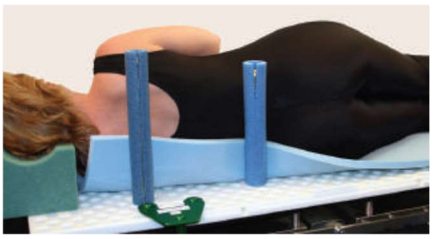




4. Tighten the locking cap to lock into the peg hole.



5. Place covered pegs into the board based on surgeon preference:

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 sheer and increase pressure redistribution.

HANDLING

Always handle Innovative Medical Product TUFF*ease* 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

TUFF*ease* 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. TUFF*ease*® 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

TUFF*ease* 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

TUFF*ease*® 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.**

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UDI

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