Instructions For Use

Humbles LapWrap®

Humbles LapWrap® Extensions

Catalog Number   **904-G, 904-G EX**

Doc Title   **IFU-IMP-0027**

Version   **0**

IMP

Intended Use/Intended Users: Humbles LapWrap is a medical device to be used to secure patients' arms by their sides during surgery. Orthopedic surgeons are the intended users.

Target Patient Group: Humbles Lapwrap is universally sized to accommodate any patient. LapWrap Extensions can be used for bariatric patients.

Contraindications: Humbles LapWrap should NOT be used to hold a patient in Trendelenburg or Reverse Trendelenburg positions.

Warnings/Precautions
- Do not use device in a manner that doesn't follow these instructions for use.
- Untrained personnel - review and understand the IFU
- Incorrect set up – follow IFU
- Max number of reuses:
  - Single use

Risks:
- Hooks could break
- Fabric could discolor when exposed to light

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
904-G	Humbles LapWrap®	00696588003559
904-G-EX	Humbles LapWrap® Extensions	00696588003566

Consumables: Not Applicable

Disposal of unit:
Humbles LapWraps 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.

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	ISO 15223-1:2016

Symbol	Title	Description	Standard
		or lot can be identified.	
REF	Catalog number	Indicates the manufacturer's catalogue number so that the medical device can be identified. The manufacturer's catalogue number shall be placed after or below the symbol and adjacent to it.	ISO 15223-1:2016
⚠	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.		
📖i	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
🏭	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:

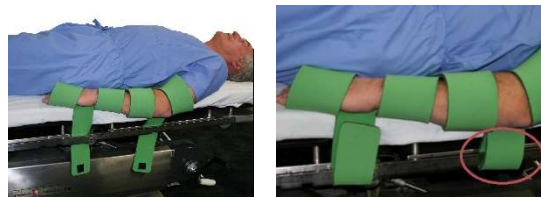|	
1. Place LapWrap® on OR table pads, black hook fastener side UP.	2. Place patient so the upper edge of the LapWrap® is located in the axillary region.

3. Wrap entire 3 piece strap around the patient's arm and attach hook-and-loop fastener near or under patient.	4. For unusual table positions, patient can be secured to the table by placing center tongue between OR table and side rail. Wrap tongue around side rail and attach black hook strap to green loop.

For Bariatric Patients

1. Lift LapWrap® center tongue of the upper arm and pull between the torso and the biceps.	
2. Insert the tongue out through the cutout, while pulling the hook-and-loop fastener around the outer arm and towards the body.	
3. Fasten to the center tongue.	

Use of extentions are used to secure arms of the extremely obese patient

1. After properly positioning patient on Lapwrap®, attach the extensions to the center tab.	2. Pull extension between the patient's arm and torso
3. Pull extension through the cut out of the LapWrap® wing.	4. Fasten the wing to the center tongue
5. If necessary, remove excess extension with standard scissors	

Optional for additional security

6. Remove hook from extension and place hook on the opposite side of extension	7. Position extension between side rail and OR table.

8. Lock extension back down on green loop. Patient is now secured to the OR table.
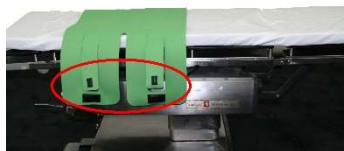

Optional Technique

Place TUFFease® pressure reducing gel pad on OR table for extra patient protection.

Safety Test ⚠ 📖ℹ

Check that black hook is securely attached to green loop material at all locations.

Cleaning and Sterilization Procedure   Not applicable – single use

Scan for additional documentation

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CE ② ⊘LATEX

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