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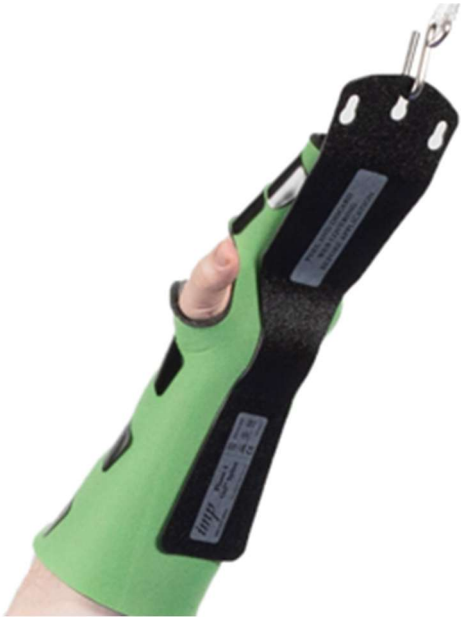
Instructions For Use

Non-Sterile Phase 4 Gel® Splint



Catalog Number **509-P4-NSP**

Doc Title **IFU-IMP-0029**

Revision **02**

Intended Use/Intended Users:
The Phase 4 Gel® Splint is a medical device to be used to protect against skin breakdown, to hold the patient's arm by adhesion rather than compression and to control internal and external rotation while holding the arm securely in place**.**

Target Patient Group: Patients requiring shoulder arthroscopy.

Contraindications:
Do not use the device:
- On patients with known sensitivity to gel
- On open wounds without appropriate protective dressing

Warnings/Precautions
- Always follow the Instructions for Use (IFU) for proper setup and correct product usage.
- Untrained personnel must review and understand the IFU
- Do not use if gel is dirty
- Improper application may result in nerve injury, impaired circulation, or pressure injuries
- Do not apply excessive pressure or secure too tightly
- Monitor patient regularly for signs of discomfort, numbness, or skin irritation
- Discontinue use if device integrity is compromised

Risks
- Avoid contact with sharp instruments that may puncture the device
- Pressure injuries may occur with prolonged use or improper positioning
- Impaired circulation: Caused by excessive pressure or incorrect placement
- Skin irritation or allergic reaction: From contact with device materials
- Slippage or inadequate stabilization: May result in unintended movement or injury

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
509-P4-NSP	Phase 4 Gel® Splint - Non-Sterile	00696588003627

Consumables: Not Applicable

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.

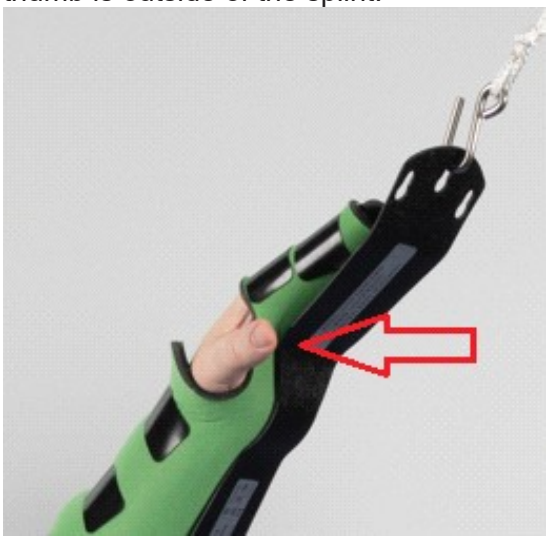
Symbol Glossary

Symbol	Title	Description	Standard
EC REP	Authorized Representative in the European Community	Indicates the authorized representative in the European Community.	ISO 15223-1:2021
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 identified. The manufacturer's catalog number shall be placed after or below the symbol and adjacent to it.	ISO 15223-1:2021
	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
	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
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1:2021
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1:2021
	Manufacturer	This symbol shall be accompanied by the name and address of the manufacturer.	ISO 15223-1:2021
MD	Medical device		ISO 15223-1:2021
	Not made with natural rubber latex		Manufacturer defined
UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1:2021

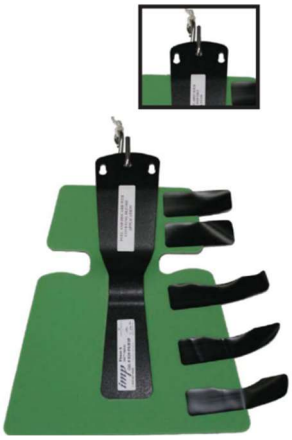
Sterile Draping Technique Utilizing Hospital Supplied Barriers

1. Peel and discard web covering before application

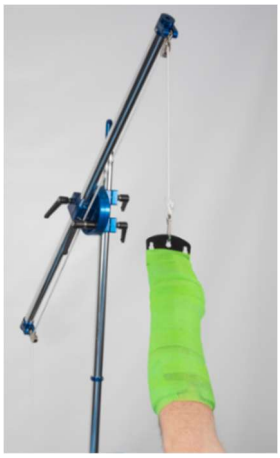
2. Place patient's arm into the gel splint and fasten hook and loop straps. Ensure that the thumb is outside of the splint.



3. Attach hook in applicable location. Three holes allow for different hook placement to control rotation.



4. Apply sterile barrier using hospital recommended guidelines



Safety Test

1. Make sure the non-sterile gel splint is covered by sterile barrier.
2. Check hook attachment.

Scan for additional documentation

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UDI

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