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Instructions For Use

Non-Sterile Phase 4 Gel® Splint

Catalog Number **509-P4-NSP**

Doc Title **IFU-IMP-0029**

Version **0**

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: This device is not designed, sold, or intended for use except as indicated.

Warnings/Precautions

- Do not use device in a manner that does not follow these instructions for use.
- Follow IFU for proper setup
- Do not use if gel is dirty

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

Innovative Medical Products
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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 15223-1:2016
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

Sterile Draping Technique Utilizing Hospital Supplied Barriers

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

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

3. 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.

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Scan for additional documentation

UDI

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