Positioned to Perform

Innovative Medical Products®

Instructions For Use

IMP® Rail Clamp

Catalog Number **409**

Doc Title **IFU-IMP-0015**

Revision **02**

Intended Use/Intended Users: The IMP Rail clamp was designed to accept a standard round or flat bar for placement of bars and accessories. Orthopedic surgeons are the intended users.

Target Patient Group: This product is an accessory to the OR Table.

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

Warnings/Precautions

- Do not use device in a manner that doesn't follow these instructions for use
- Untrained personnel - review and understand the IFU
- Do not install across different rail sections
- Clamp won't lock to rail without first inserting an accessory
- Do not strike clamp
- Max number of reuses:
    - Until movement is hindered and unrepairable

Risks:

- Highly acidic or basic cleaners strip anodize
- Clamp may be damaged if it is cleaned with bleach

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	UDI-DI
409	IMP® Rail Clamp	00696588001302

Consumables: N/A

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.

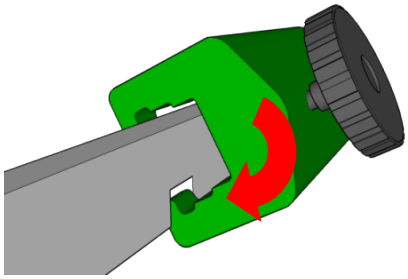
Symbol Glossary

Symbol	Title	Description	Standard
EU REP	Authorized Representative in the European Community	Indicates the authorized representative in the European Community	ISO 15223-1:2021

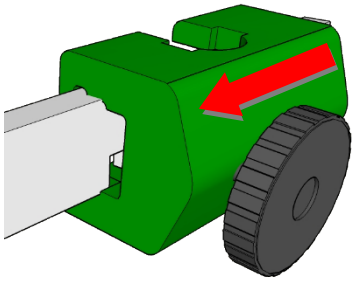
Symbol	Title	Description	Standard
	Batch Number	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1:2021
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified. The manufacturer's catalogue number shall be placed after or below the symbol and adjacent to it	ISO 15223-1:2021
	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
	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
	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
	Serial Number	The manufacturer's serial number shall be placed after or below the symbol and adjacent to it	ISO 15223-1:2021
	Unique device identifier		ISO 15223-1:2021

Instructions for Use:

1. Drop clamp into side rail opening

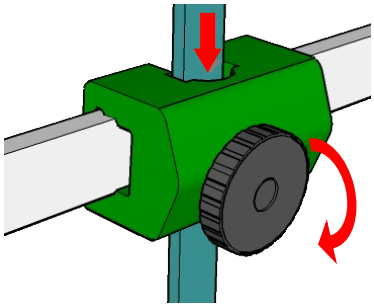


2. Slide to desired position

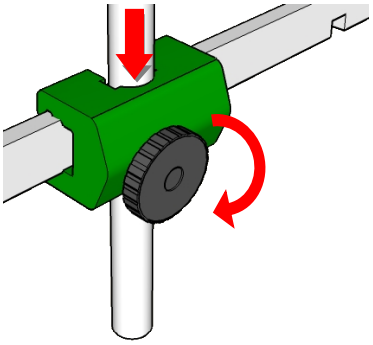


3. Insert bar component

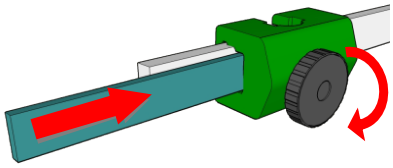
Flat bar



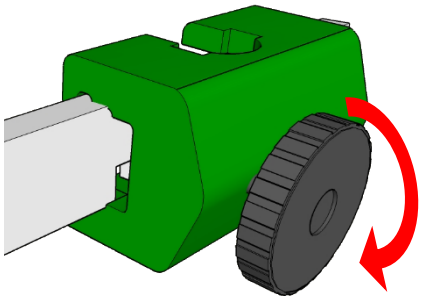
Round bar



Flat bar horizontal extension

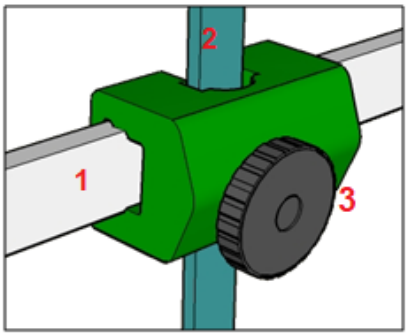


4. Turn clockwise to tighten knob



Safety Test

1. Check clamp is seated firmly to side rail
2. Check bar component is inserted properly
3. Ensure knob is tightened securely



Cleaning and Sterilization Procedure

NOTE: ALL SOLUTIONS MUST BE COMPATIBLE WITH ALUMINUM & STAINLESS STEEL

Recommended Washer / Decontaminator Instructions:
• Soak the product in an enzyme solution. Follow the manufacturer's direction for dilution and soaking time.
• Put through washer / decontaminator according to manufacturer's instructions with a detergent up to a PH of 9.0
• **NOTE: SELECT CYCLE THAT DOES NOT INCLUDE LUBRICATION**
• Recommended Hand Cleaning Instructions:
• Pre-Soak the product / components in an enzyme solution. Follow the manufacturer's direction for dilution ratio and soaking time.
• Rinse the product in warm tap water.
• Wash the product with an instrument detergent **up to a pH of 9.0**.
• Rinse the product in warm tap water.
• Soak or wipe the product down with a hospital approved and / or EPA approved germicide according to instructions.
• Rinse the product in warm tap water.
• Dry thoroughly and wrap.

Recommended Hand Cleaning Instructions:
• Pre-Soak the product / components in an enzyme solution. Follow the manufacturer's direction for dilution ratio and soaking time.
• Rinse the product in warm tap water.
• Wash the product with an instrument detergent up to a pH of **9.0** or enzyme product
• Rinse the product in warm tap water
• Soak or wipe the product down with a hospital approved and / or EPA approved germicide according to instructions.
• Rinse the product in warm tap water

- Dry thoroughly and wrap

Scan for additional documentation

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