



Instructions For Use

IMP[®] Rail Clamp

Catalog Number **409**

Doc Title **IFU-IMP-0015**

Version **0**



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

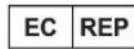
Risks:

- 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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 info@IMPmedical.com



Advena Ltd
 Tower Business Centre, 2nd Flr,
 Tower Street, Swatar, BKR 4013 Malta

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

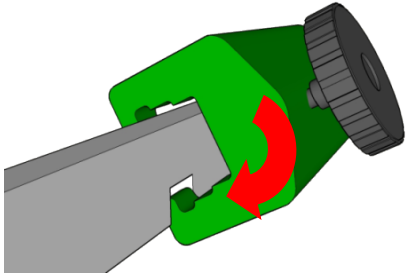
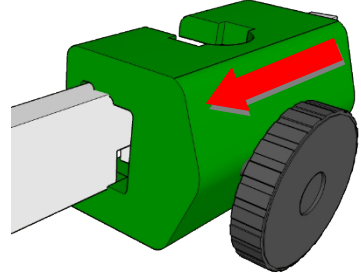
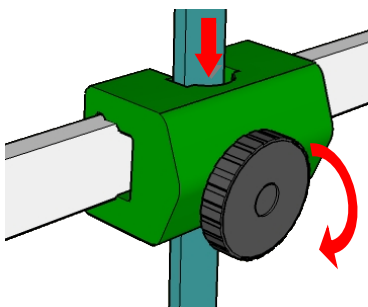
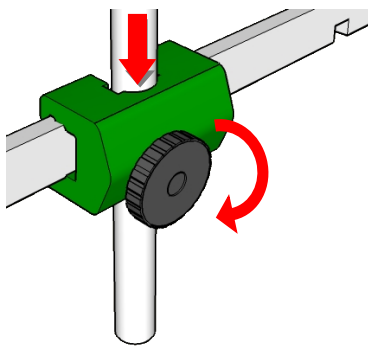
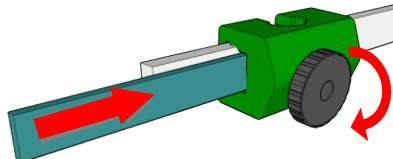
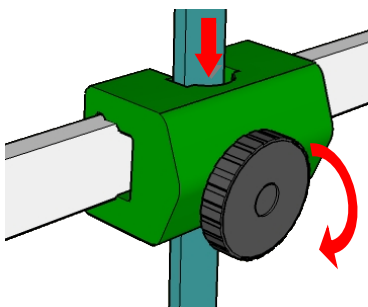
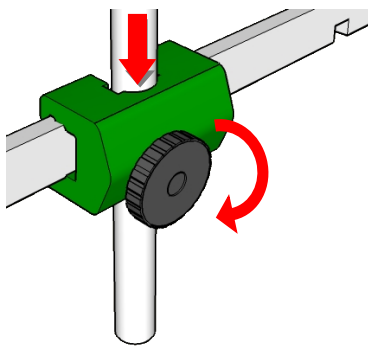
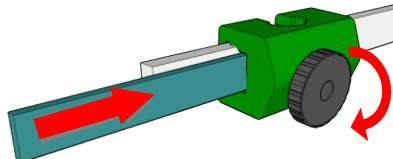
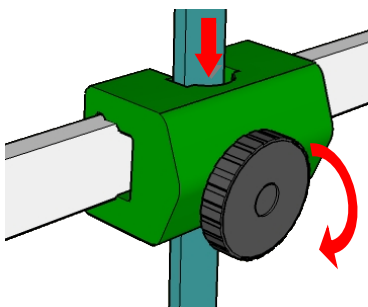
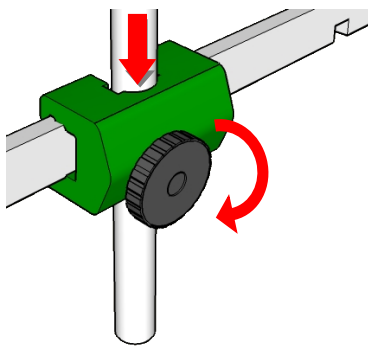
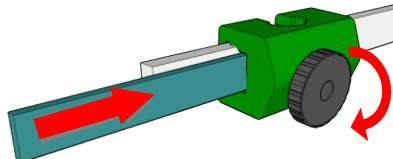
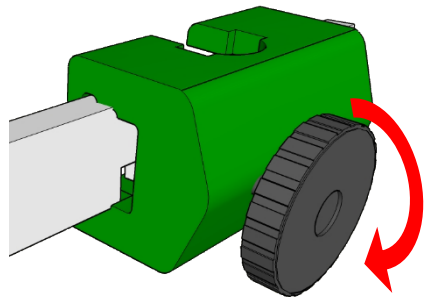
| Symbol | Title | Description | Standard |
|--------|---|---|------------------|
| | Authorized Representative in the European Community | Indicates the authorized representative in the European Community | ISO 15223-1:2016 |
| | Batch Number | Indicates the manufacturer's batch code so that the batch | ISO 15223-1:2016 |



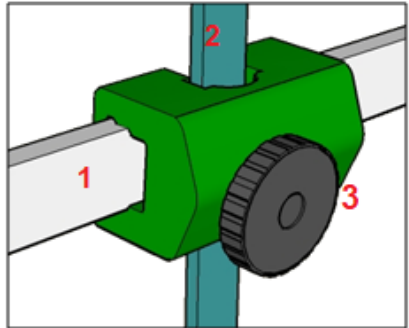


| Symbol | Title | Description | Standard |
|--------|------------------------------------|---|----------------------|
| | | or lot can be identified | |
| | Catalogue number | Indicates the manufacturer's catalogue number so that the medical device can be identified. The manufacturer's catalogue number shall be placed after or below the symbol and adjacent to it | ISO 15223-1:2016 |
| | 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 |
| | 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 |
| | Manufacturer | This symbol shall be accompanied by the name and address of the manufacturer | ISO 15223-1:2016 |
| | Medical device | | ISO 15223-1:2016 |
| | 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 15223-1:2016 |
| | Unique device identifier | | ISO 15223-1:2016 |



Instructions for Use:

| | | | | |
|---|--|--|---|--|
| <p>1. Drop clamp into side rail opening</p>  | <p>2. Slide to desired position</p>  | | | |
| <p>3. Insert bar component</p> <table border="0"><tr><td data-bbox="138 703 527 1165"><p>Flat bar</p></td><td data-bbox="527 703 998 1165"><p>Round bar</p></td><td data-bbox="998 703 1479 1165"><p>Flat bar horizontal extension</p></td></tr></table> | | <p>Flat bar</p>  | <p>Round bar</p>  | <p>Flat bar horizontal extension</p>  |
| <p>Flat bar</p>  | <p>Round bar</p>  | <p>Flat bar horizontal extension</p>  | | |
| <p>4. Turn clockwise to tighten knob</p>  | | | | |

| | |
|---|---|
| <p>Safety Test  </p> <ol style="list-style-type: none">1. Check clamp is seated firmly to side rail2. Check bar component is inserted properly3. Ensure knob is tightened securely |  |
|---|---|



Cleaning and Sterilization Procedure

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

| Recommended Washer / Decontaminator Instructions: |
|---|
| <ul style="list-style-type: none"> Soak the product in an enzyme solution. Follow the manufacturer's direction for dilution and soaking time. |
| <ul style="list-style-type: none"> Put through washer / decontaminator according to manufacturer's instructions with a detergent up to a PH of 9.0 |
| <ul style="list-style-type: none"> NOTE: SELECT CYCLE THAT DOES NOT INCLUDE LUBRICATION |
| <ul style="list-style-type: none"> Recommended Hand Cleaning Instructions: |
| <ul style="list-style-type: none"> Pre-Soak the product / components in an enzyme solution. Follow the manufacturer's direction for dilution ratio and soaking time. |
| <ul style="list-style-type: none"> Rinse the product in warm tap water. |
| <ul style="list-style-type: none"> Wash the product with an instrument detergent up to a pH of 9.0. |
| <ul style="list-style-type: none"> Rinse the product in warm tap water. |
| <ul style="list-style-type: none"> Soak or wipe the product down with a hospital approved and / or EPA approved germicide according to instructions. |
| <ul style="list-style-type: none"> Rinse the product in warm tap water. |
| <ul style="list-style-type: none"> Dry thoroughly and wrap. |

| Recommended Hand Cleaning Instructions: |
|---|
| <ul style="list-style-type: none"> Pre-Soak the product / components in an enzyme solution. Follow the manufacturer's direction for dilution ratio and soaking time. |
| <ul style="list-style-type: none"> Rinse the product in warm tap water. |
| <ul style="list-style-type: none"> Wash the product with an instrument detergent up to a pH of 9.0 or enzyme product |
| <ul style="list-style-type: none"> Rinse the product in warm tap water |
| <ul style="list-style-type: none"> Soak or wipe the product down with a hospital approved and / or EPA approved germicide according to instructions. |
| <ul style="list-style-type: none"> Rinse the product in warm tap water |
| <ul style="list-style-type: none"> Dry thoroughly and wrap |

Scan for additional documentation





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