1. **Introduction**
Hayden Medical Rigid Arms and accessories are a manually adjustable device assembly. The Arms are available with Columns in straight or angled configurations.

2. **Intended Use**
2.1 Hayden Medical Rigid Arms and accessories are intended for use in a sterile setting to hold and position retractors as well as other instruments during surgery.
2.2 Hayden Medical Rigid Arms and accessories are intended to be used by licensed practicing physicians. It is also expected that clinical assistants are knowledgeable in setting up these instruments.

3. **Contraindications**
This product is not intended for use except as indicated.

4. **Warnings**
4.1 US Federal law restricts this device to sale by or on the order of a physician.
4.2 The products will be delivered non sterile. Prior to initial use, and each following use, the products must be cleaned and sterilized per section 9 of this IFU, as well as checked for visible irregularities and malfunctions according to the instructions given in section 8 of this IFU.
4.3 End of life is normally determined by wear and damage due to use.
4.4 Use of this instrument for any purpose, or in any manner other than those described here may cause instrument damage or failure which could result in serious patient injury or death. If needed, all Hayden Medical metal products or fragments thereof can be located by means of an X-Ray.
4.5 To maintain intended clamping capacity of the table clamp, do not tighten the clamping knob when the Martin's Arms column is not fully installed.
4.6 DO NOT FORCE ANY KNOB PAST STOP.
4.7 **THE RAIL CLAMPS ARE NOT INSULATED. DO NOT USE THE SYSTEM WHEN GROUNDING A PATIENT IS UNACCEPTABLE!**

5. **Possible Adverse Effects**
Injury, infection, and delayed surgical procedure.

6. **Product Description and Use**
6.1 Fixed Hayden Medical Table Clamp
Provides an attachment point to the operating table rail. Accepts and holds the column of the Martin's Arms in position.

To attach to the rail:
1. Open rail clamping knob until the L-brackets fit over the rail, then tighten to secure.
2. Insert column of the Martin's Arms into column opening and tighten the column clamping knob when arm is in desired position.

6.2 Rotatable Hayden Medical Table Clamp
Provides an attachment point to the operating table rail. Accepts and holds the column of the Martin's Arms in position and allows for full range of rotation.

To attach to the rail:
1. Open the rail clamping knob until the L-brackets fit over the rail, then tighten to secure.
2. Insert the column of the Martin's Arms into column opening, adjust the column to the desired angle, and tighten the column clamping knob when the arm is in desired position.

6.3 Hayden Medical Quick Connection Accessories
Provides a fast connection point for accessories to the distal end of the Martin's Arms. Depending on customer preference, Martin's Arms can come with the following quick connect chucks:

A. Squared Shaft Quick Connect
B. Hex Shaft Quick Connect
C. Tight Twist Hex Shaft Quick Connect
D. Tight Twist Square Shaft Quick Connect

These quick connect chucks are not interchangeable and can only be used with the appropriate Hayden Medical Quick Connection Shaft.

To attach the square shaft quick connect accessories:
1. Turn collar clockwise and pull back.
2. Insert the accessory shaft into the chuck until fully seated (rotate to clock flats on shaft with inside square).
3. Let the collar spring forward and turn counterclockwise to lock. Check to see that the shaft is secured, and the collar is in locked position.
To unlock, reverse the above steps.

To attach the hex shaft quick connect accessories:
1. Push the sliding collar forward.
2. Insert the accessory shaft into the chuck until fully seated (rotate to clock flats on shaft with inside).
3. Pull the collar back to lock. Check to see that shaft is secured and the collar is in locked position.
To unlock, reverse the above steps.

To attach to tight twist hex or square shaft quick connect accessories:
1. Twist collar counterclockwise.
2. Insert the accessory shaft into chuck until fully seated (rotate to clock flats on shaft with inside).
3. Twist the collar clockwise to lock the quick connect accessory into place. Check to see that the shaft is secured and the collar is in locked position.
To unlock, reverse the above steps.

6.4 Martin's Arms
Provides five point positioning of the attached accessories into the surgical field. Attaches to either a Straight or L-Column.

To position and lock in place:
1. Support the distal end with one hand and loosen the central tightening knob by turning counterclockwise.
2. Position the attached accessory as needed and turn knob clockwise to lock in place. Check to see that Martin's Arms is secure enough to hold position.
To loosen, reverse the above steps.

CAUTION: When loosening, do not force knob past stop.

7. **Inspection Before Use**
All Hayden Medical products should be inspected througout its lifetime to ensure proper function and performance. If product does not pass inspection, do not use. Send product back to Hayden Medical for repair immediately.

Martin's Arms
1. Visually inspect instruments for damage or cracks.
2. Check to make sure that arm becomes rigid at all three joints by turning central tightening knob clockwise.
3. Insert arm column into table clamp, turn column clamping knob clockwise and ensure that it hold securely.
4. Check quick connect distal end to make sure the collar locks and unlocks accessory securely.

Hayden Medical Quick Connection Accessories
1. Visually inspect instruments for damage or cracks.
2. Quick Connect Shaft should freely engage and disengage in and out of the quick connect distal end.
3. Clamp Screw on Quick Connect Accessory should be able to open and close fully without moving on its own.

Hayden Medical Table Clamps
1. Visually inspect instruments for damage or cracks.
2. L-brackets on Hayden Medical Table Clamp should clamp securely to table rail.
3. Insert Martin's Arms into column opening, turn central tightening knob clockwise and make sure the post is held securely inside the column opening.

8. **Reprocessing:**
1. The following validated reprocessing steps should be used for reprocessing Hayden Medical products. Other methods used for reprocessing Hayden Medical devices shall be validated by the user prior to implementation.
2. The color of Hayden Medical 's aluminum instruments may vary due to the anodizing process or alloy used. Shading or loss of color may also occur after sterilization. This is not a defect in the instruments or material and will not affect the performance of your high quality Hayden Medical instrument.

8.1 Cleaning Instructions
Point of Use:
1. Directly after use, remove coarse contamination from the instrument and keep the instrument moist for transit to the processing site. Prior to cleaning and sterilization do not use any fixing agents or hot water > 104°F (>40°C) as this may lead to the fixation of residue and interfere with the cleaning process.
2. Where applicable, multi-component instruments should be disassembled for appropriate cleaning. Care should be exercised to avoid losing small components.
3. Perform cleaning as soon as is reasonably practical following use. Allowing instrumentation to dry with fluids and debris may result in staining, corrosion, and increased difficulty in the removal of contaminants.
4. During the transport of instruments to the processing site, store contaminated instruments securely in a closed container to avoid damage to the instrument and/or contamination of the environment.

Supplies and Equipment Needed for Cleaning:
- Ultrasonic Cleaner
- Pre-cleaning and Manual Cleaning enzymatic, pH neutral cleaner, such as: Prolystica 2X concentrate Enzymatic Pre-Soak and Cleaner
- Soft Nylon Bristle Brush such as 3-1000 Integra Miltex Premium Grade Nylon Bristle Brush should be used for exterior surface cleaning. For internal cleaning, a brush size appropriate to the lumen inner diameter (ID) should be used.
- Automated cleaning enzymatic, pH Neutral cleaner such as: Prolystica 2X concentrate Enzymatic Pre-Soak and Cleaner.
- Tap, deionized (DI), Reverse Osmosis (RO), or filtered water for processing.

Cleaning Preparation
For both Manual and Automated cleaning, all instruments, apart from the articulating arm, should be cleaned in the open or unlocked position.
- Articulating Arms: Turn tightening knob clockwise to tighten ball joint prior to placing arm in sonicator. The knob should be tightened enough to prevent manipulation of the arm.

For the purposes of this IFU, the table below defines cold, lukewarm, and hot water temperatures.

For the purposes of this IFU, the table below defines cold, lukewarm, and hot water temperatures (per AAMI TIR12).

Temperature Description	°Celsius	°Fahrenheit
Cold	<22°C	<72°F
Lukewarm	22°-43°C	72°-110°F
Hot	>43°C	>110°F

CAUTION:
1. Automated cleaning is not suitable for Martin's Arms or Quick Connect Accessory (115-306QC).
Automated cleaning may only be used for Hayden Medical table clamps and Hayden Medical quick connect accessories, excluding 115-306QC.

A. Manual Cleaning Instructions
1. Rinse each instrument individually with a steady stream of lukewarm tap water for a minimum of 2 minutes or until gross contaminants are removed.
2. Place each instrument into an ultrasonic cleaner containing a solution of enzymatic, pH neutral detergent prepared according to the detergent manufacturer's instructions, using lukewarm tap water, sonicate for 10 minutes.

3. In a manual wash container, prepare an enzymatic, pH neutral detergent solution with lukewarm tap water per detergent manufacturer instructions.
4. Transfer each instrument from the ultrasonic cleaner to the manual wash container and fully immerse in the cleaning solution prepared in Step 3.
5. While still submerged, any visible contamination and debris should be removed by scrubbing each instrument with a soft nylon bristle brush for a minimum of 1 minute, until visibly clean, paying particular attention to hard to clean areas such as crevices and joints.
6. Rinse each instrument with lukewarm tap water for a minimum of 2 minutes or until no visible soil remains.
7. Dry each instrument using clean, absorbent, lint-free wipes, or pressurized air, to remove excess rinse water.

B. Automated Cleaning

Use only washer/disinfector machines that have been validated in accordance with ISO 15883.

1. Perform pre-cleaning to remove gross contaminants as follows:
   a. Rinse with running, lukewarm, DI, RO, or filtered water for a minimum of 1 minute for each instrument to remove gross contaminants.
2. In a manual wash container, prepare an enzymatic, pH neutral detergent wash solution, per detergent manufacturer instructions, using lukewarm tap water. Submerge and soak instruments in wash solution for a minimum of 1 minute.
3. While still submerged, remove visible soil by scrubbing with a soft nylon bristle brush for a minimum of 4 minutes or until no visible soil is observed.
4. Rinse with running, lukewarm DI, RO, or filtered water for a minimum of 1 minute for each instrument.
5. Load instruments into washer/disinfector in accordance with the manufacturer's instructions.
6. Arrange instruments with curved surfaces and cannulations facing downward to prevent pooling of water on the instrument.
7. Operate that washer/disinfector cycle according to the manufacturer's instructions.

Recommended minimal automated washer/disinfector parameters:

- Heated wash at 140°F (60°C) for 2 minutes using an enzymatic, pH neutral cleaner such as Prolystica Ultra Concentrate Enzymatic Cleaner.
- Heated tap water rinse at 140°F (60°C) for 20 seconds.
- Heated deionized water rinse at 180°F (82°C) for 2 minutes.
- Forced air drying at 240°F (116°C) for 9 minutes.

Post Cleaning Inspection:

After cleaning, visually inspect each instrument with the naked eye under normal lighting conditions to determine if all visible soil (e.g., blood protein substances and other debris) has been removed. If any soil is still visible, repeat cleaning steps.

8.2 Sterilization Instructions

A. Note

1. For instruments with moving parts, lubricate joints with a steam-permeable, water-soluble instrument lubricant prior to sterilization.
2. Instruments should be sterilized in the opened or unlocked position. Central knob of any Martin's Arms must be opened for sterilization.
3. Use only FDA cleared CSR Sterilization Wrap. Only use wrappers validated for use in double simultaneous wrapping.

B. Preparation for Sterilization

1. Each instrument should be wrapped using the simultaneous double wrapping equal fold technique.
2. Chemical indicator tape should be used to secure packaging and for labeling the contents. Note: Chemical Indicator Tape will change color or display diagonal stripes when exposed to temperatures of 121°C (250°F)

Instruments should be sterilized by standard cycles using steam with the parameters listed below:

	Sterilize Temperature	Sterilize Time	Dry Time
Gravity	121°C (250°F)	30 minutes	30-minute
Prevacuum (US)	132°C (270°F)	4 minutes	30-minute
Pre vacuum (EU)	134°C (273°F)	3 minutes	20-minute

CAUTION: Autoclave temperatures should not surpass 137°C (280°F), as the handle, insulation or other non-metallic parts may be affected. The steam autoclave manufacturer may be contacted to confirm appropriate temperature and sterilization times.

9. Storage

Instruments should be stored in a clean and dry area. Inspect each instrument prior to use for functionality and damage. When necessary, dispose of products in accordance with national regulations and approved hospital practices for surgical instrument disposal.

10. Warranty

Hayden Medical products are warranted to be free from defects in material and workmanship when used under normal conditions for its intended purpose for 5 years from invoice date. Any product that proves to be defective during this period, Hayden Medical will, at its sole discretion, either repair or replace the defective product at no charge. This limited warranty is null and void if Hayden Medical product is repaired or modified in any way by any party that is not explicitly Hayden Medical authorized. Hayden Medical shall not be held responsible for consequential or indirect damage arising from the sale of any product.

11. Complaint Handling/ Reporting

Any adverse event involving Hayden Medical products should be reported to Hayden Medical and the country specific regulatory authorities immediately. To report an event to Hayden Medical :
Call: **661-296-7200** or
Email: info@haydenmedical.com

12. Maintenance

Hayden Medical recommends that instruments be sent to Hayden Medical for preventive maintenance every 2-3 years to maximize instrument longevity. Preventive maintenance includes:
1. Replacement of wear parts
2. Instrument adjustment

Hayden Medical IFU-0001 I rev5

HAYDEN MEDICAL

Martin's Arms System

INSTRUCTIONS FOR USE

This instruction for use is only applicable for the medical instruments listed below.

Rigid Arms

115-050	115-055	115-052	115-056
115-050QC	115-052QC	115-055QC	115-056QC
115-062			

Quick Connection Accessories

115-300QC	115-305QC	115-306QC	115-308QC

Table Clamps

115-060	115-060HR	115-060R

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