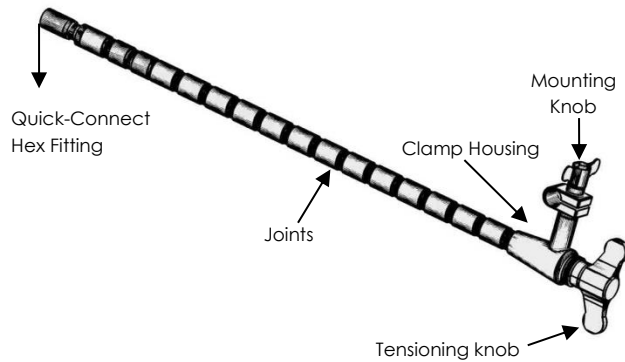


## Using FlexArm™ Plus Surgical Holders and Positioners

**WARNING:** Mediflex® FlexArm™ Plus Surgical Holders and Positioners can only be used by physicians possessing adequate training and familiarity with these types of devices.

### Parts of a FlexArm Plus, shown – 99056-QC



#### Mounting:

The FlexArm™ Plus can be mounted on a Mediflex Swivel Bar Post. To mount arm, unscrew the mounting knob. Slide the arm onto the post and tighten the mounting knob to secure the arm onto the post.

#### Using:

Turn the tensioning knob clockwise to lock the arm into the desired position. If re-positioning is required, turn the knob counter-clockwise enough to move the arm, and clockwise to lock it in the desired position again. The arm may also be manipulated in its locked state for small adjustments.

#### Sterilization & Drying

- Pre-Vac Steam Autoclave: Minimum of 4 minutes at or above 132° C up to 134°C.
- 30 minute dry time.
- Air dry, or use a soft, non-abrasive, non-linting towel.
- Validated hospital cleaning and sterilization protocol for reusable instruments may also be used.

#### Maintenance

We recommend regular lubrication of all threaded components

#### Inspection and Function Testing

- Check to be sure moving parts, including tightening devices move freely with no binding.
- Visually inspect for burs, cracks and other damage.

### Products Covered by this Document:

#### FlexArm Plus Versions

75000-1, 99000, 99054-QC, 99054, 99054-D, 99055-QC, 99055, 99055-D, 99055-DS, 99054-QCLR, 99054-LR, 99054-DLR, 99055-QCLR, 99055-LR, 99055-DLR, 99055-DSL, 99056-QC, 99056, 99056-D, 99056-QC-BSO1, 40001-01, 99000-R9, 99040, 38077, PDT-5720, PDT-5717

#### Swivel Bar Posts

69053, 69098, PDT-5719

#### Attachments / Accessories:

69099, 69703, 69704, 69705, 69706, 69706-L, 69707, 69708, 69708-MB, 69709, 69710, 69710-XL, 69735, 69735-3, 69735-XL, 69736, 69736-C, 69736-XL, 69737, 69737-XL, 69738, 72162, 72163, 72164, 69736-C-XL, 69703-R9, 69704-R9, 69705-R9, 69709-R9, 69735-C, 69736-C, 69737-C, 69735-C-XL, 69736-C-XL, 69736-C-XL-R, 69737-C-XL, PDT-5715, PDT-5708, PDT-5705, PDT-5710, PDT-5718, PDT-5716

#### Additional Information

Mediflex warrants FlexArm Plus products to the original purchaser to be free from defects in material and workmanship for a period of one (1) year from the date of purchase.

#### Symbols Used in Labeling

	Manufacturer		Catalog Number
	Lot Number		UDI Carrier Used on Label
	Non Sterile		Manufacturing Date
	Medical Device		Warnings or Precautions
	Read Instructions for use (IFU) Before Using		Authorized Representative in the European Community/European Union

*A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established*

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IFU 51 Rev. 2.3

# Mediflex®

SURGICAL PRODUCTS

## FlexArm™ Plus Surgical Holders and Positioners

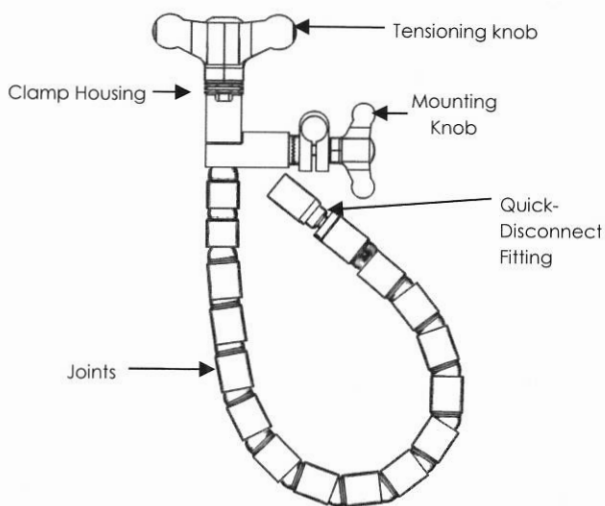
Instructions for Use

<b>Products Covered by this Document</b>	See list of REF #'s at the bottom of the document.																					
<b>WARNINGS</b>	<b>Supplied non-sterile. Must be cleaned and sterilized before use.</b>																					
<b>Intended Use</b>	The Mediflex FlexArm™ Plus is intended to hold and provide stabilization of devices during surgical procedures.																					
<b>Indications</b>	The Mediflex FlexArm™ Plus is intended for use in situations where static positioning is required.																					
<b>Contra-Indications</b>	The Mediflex FlexArm™ Plus is not intended for use in situations where static positioning is not required.																					
<b>Limitations on Reprocessing</b>	Functional life is determined by wear and damage. Repeated reprocessing has minimal effect on these devices. User will inspect device before each use to check for physical damage. End of life will be determined by wear and damage. Organization supports the use of the device for 7 years.																					
<b>INSTRUCTIONS</b>																						
<b>Point of Use</b>	Wherever possible, do not allow blood, debris or bodily fluids to dry on devices. For best results, reprocess immediately after use.																					
<b>Preparation for Cleaning</b>	Separate components that are still assembled. Examples: <ul style="list-style-type: none"> <li>• Remove any accessory attached to the Quick-Disconnect tip.</li> <li>• Remove the FlexArm Plus from the post it may be mounted on.</li> <li>• Turn the tensioning knob counterclockwise all the way so that it is in its relaxed state.</li> </ul>																					
<b>Cleaning: Automated</b>	Mediflex's validated washer-disinfector parameters, using Polystyca 2X Concentrate Alkaline Detergent are: <table border="1"> <thead> <tr> <th>Phase</th> <th>Time(minutes)</th> <th>Temperature (°C)</th> </tr> </thead> <tbody> <tr> <td>Pre-wash</td> <td>2:00</td> <td>Cold Water</td> </tr> <tr> <td>Wash 1</td> <td>5:00</td> <td>51.6</td> </tr> <tr> <td>Rinse 1</td> <td>2:00</td> <td>Hot Water</td> </tr> <tr> <td>Rinse 2</td> <td>2:00</td> <td>Hot Water</td> </tr> <tr> <td>Final Rinse</td> <td>1:00</td> <td>90</td> </tr> <tr> <td>Drying</td> <td>30:00</td> <td>90</td> </tr> </tbody> </table>	Phase	Time(minutes)	Temperature (°C)	Pre-wash	2:00	Cold Water	Wash 1	5:00	51.6	Rinse 1	2:00	Hot Water	Rinse 2	2:00	Hot Water	Final Rinse	1:00	90	Drying	30:00	90
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<b>Cleaning: Manual</b>	<ul style="list-style-type: none"> <li>• Prepare an enzymatic detergent (such as Enzol) according to manufacturer's recommendations (7.8ml/L as there is no dried soil expected on the devices) at 40°C and soak device(s) for fifteen minutes.</li> <li>• Scrub the submerged device(s) with a soft bristled, non-metallic brush. Agitate the device(s) by hand while scrubbing for one minute total, for each device.</li> <li>• Rinse device(s) with warm tap water for thirty (30) seconds.</li> <li>• Place device(s) into bath containing warm (38-49°C) water. Agitate the device(s) by hand for one (1) minute. Repeat 2 additional times.</li> <li>• Sonicate device(s) for fifteen (15) minutes in 40°C water and a neutral P.H. detergent (such as Neutrad™). Prepare detergent according to manufacturer's recommendations.</li> <li>• Rinse device(s) with clean tap water for one (1) minute.</li> <li>• Repeat this cleaning procedure if the instrument has any sign of visible soil remaining.</li> </ul>																					

## Using FlexArm Surgical Holders and Positioners

**WARNING:** Mediflex FlexArm Surgical Holders and Positioners can only be used by physicians possessing adequate training and familiarity with these types of devices.

### Parts of a FlexArm, shown – 69056-QC



#### Sterilization & Drying

- Pre-Vac Steam Autoclave: Minimum of 4 minutes at or above 132° C up to 134°C.
- 40 minute dry time.
- Air dry, or use a soft, non-abrasive, non-linting towel.
- Validated hospital cleaning and sterilization protocol for reusable instruments may also be used.

#### Maintenance

We recommend regular lubrication of all threaded and hinged components.

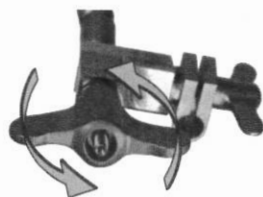
#### Inspection and Function Testing

- Check to be sure moving parts, including tightening devices move freely with no binding.
- Visually inspect for burs, cracks and other damage.

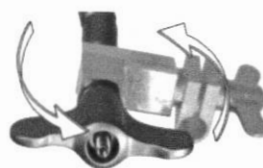
#### Additional Information

Mediflex warrants FlexArm products to the original purchaser to be free from defects in material and workmanship for a period of one (1) year from the date of purchase.

### Preparing the arm for Cleaning and Sterilization

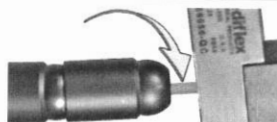


**Step 1.** Turn the **Tensioning Knob** (shown in Blue) Counter Clockwise until it stops. This enables the internal cable to relax.



**Step 2.** To create space in the arm which allows steam or other sterilizing media to enter that space, hold the flexible arm in a "U" shape and turn the **Clamp Housing** (shown in Yellow) Counter Clockwise 5 – 6 rotations.

**Step 3.** If steps 1 and 2 were done correctly, there should be a gap of ¼" and ⅜" (6.2mm and 9.4mm) between the Clamp Housing and the first ball and socket joint and the internal cable should be visible (shown in Pink.)



### Pretensioning and Tightening the Arm in Surgery

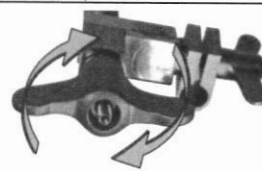


**Step 1.** Turn the **Tensioning Knob** (shown in Blue) Clockwise until it stops. This is to be sure that the internal cable is in the proper position for Step 2.



**Step 2.** Hold the flexible arm in a "U" shape and turn the **Clamp Housing** (shown in Yellow) Clockwise until you meet resistance. **CAUTION:** If done incorrectly, Flex Arm Device will not perform as expected.

**Step 3** The arm is made stiffer by turning the **Tensioning Knob** (shown in Blue) Clockwise as shown below. The arm is made less stiff by turning the **Tensioning Knob** Counter Clockwise as shown in Step 1.



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A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established

IFU 12 Rev. 3.2

**Mediflex**<sup>®</sup>  
SURGICAL PRODUCTS

FlexArm™ Surgical Holders and Positioners



Instructions for Use

**Products Covered by this Document**

See list of REF #'s at the bottom of the document.

**WARNINGS**



**Supplied non-sterile. Must be cleaned and sterilized before use.**

**Intended Use**

The Mediflex FlexArm™ is intended to hold and provide stabilization of devices during surgical procedures.

**Limitations on Reprocessing**

Functional life is determined by wear and damage. Repeated reprocessing has minimal effect on these devices. User will inspect device before each use to check for physical damage. End of life will be determined by wear and damage. Organization supports the use of the device for 7 years.

**Indications for Use**

The Mediflex Monolithic FlexArms are intended for use in situations where static positioning is required.

**Contra-Indications**

The Mediflex Monolithic FlexArms is not intended for use in situations where static positioning is not required.

#### INSTRUCTIONS

**Point of Use**

- Do not allow blood, debris or bodily fluids to dry on devices. Reprocess immediately after use.

**Preparation for Cleaning**

Separate components that are connected. Examples:

- Remove any accessory attached to the Quick-Disconnect tip.
- Remove the FlexArm from the post it may be mounted on.

See "Preparing the arm for cleaning and sterilization" for additional information.

**Cleaning: Automated**

Mediflex's validated washer-disinfector parameters, using Polystica 2X Concentrate Alkaline Detergent are:

Phase	Time(minutes)	Temperature (°C)
Pre-wash	2:00	Cold Water
Wash 1	5:00	51.6
Rinse 1	2:00	Hot Water
Rinse 2	2:00	Hot Water
Final Rinse	1:00	90
Drying	30:00	90

**Cleaning: Manual**

- Prepare an enzymatic detergent (such as Enzol) according to manufacturer's recommendations (7.8ml/L as there is no dried soil expected on the devices) at 40°C and soak device(s) for fifteen (15) minutes.
- Scrub the submerged device(s) with a soft bristled, non-metallic brush. Agitate the device(s) by hand while scrubbing. Maneuver any movable parts to loosen soil for one minute total, for each device.
- Rinse device(s) with warm tap water for thirty (30) seconds.
- Place device(s) into bath containing warm (38-49°C) water. Agitate the device(s) by hand for one (1) minute. Repeat 2 additional times.
- Sonicate device(s) for fifteen (15) minutes in 40°C water and a neutral pH detergent (such as Neutrad™). Prepare detergent according to manufacturer's recommendations.
- Rinse device(s) with clean tap water for one (1) minute, dry the device(s) with a clean, lint-free cloth.
- Inspect for visible soil or debris. Repeat cleaning procedure if the device(s) appear to be soiled.

**Products Covered by This Document**

**FlexArm Arms:**

69056, 69056-BS01, 69056-D-BS01, 69056-D, 69056-QC ,  
69056-QC-BS01, 69303-AD, 69303-AQC, 69303-BSQC, 69303-AS,  
69072, 69073











**FlexArm Kits:**

69054, 69054-D, 69054-DLR, 69054-LR, 69054-QCLR, 69054-QC,  
69054-QC-BS01, 69054-QCLR-BS01, 69055, 69055-D, 69055-DS,  
69055-LR, 69055-DLR, 69055-DSLR, 69055-QCLR, 69055-QCLR-BS02,  
69055-QC, 69055-QC-BS02

**Attachments/Accessories:**

69053, 69098, 69099, 69706, 69707, 72155, 72162, 72163

**Symbols Used in Labeling**

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