# Operator's Manual

# Grid Holder CX

# For use with Breast SPEEDER CX and

# Canon 1.5T MRI Systems

www.qualityelectrodynamics.com

| Canon Model # | QED REF |
|---|---|
| MJCA-257A | MAC000110 |

**Warranty and Liability**

The responsibility for maintenance and management of the product after delivery resides with the customer who has purchased the product. The warranty does not cover the following items, even during the warranty period:

- Damage or loss due to misuse or abuse.
- Damage or loss caused by Acts of God such as fires, earthquakes, floods, lightning, etc.
- Damage or loss caused by failure to meet the specified conditions for this equipment, such as inadequate power supply, improper installation, or unacceptable environmental conditions.
- Damage due to changes or modifications made to the product.

In no event shall QED be liable for the following:

- Damage loss or problems caused by relocation, modification, or repair performed by personnel not explicitly authorized by QED.
- Damage or loss that results from negligence or from ignoring the precautions and operating instructions contained in this operation manual.

**Transportation and Storage Conditions**

This equipment shall be transported and stored under the following conditions:

| | | |
|---|---|---|
|  | Temperature | -10°C to +50°C |
|  | Relative humidity | 20% to 95% |
|  | Atmospheric pressure | 700 hPa to 1060 hPa |

Shock indicators for monitoring transport are affixed to the packaging. If the shock indicator is activated as shown by a red color inside the glass tube, the coil was not handled with the required care. However, an activated shock indicator does not necessarily indicate damage to the coil.

| | |
|---|---|
|  CAUTION | If the coil packaging is exposed to environmental conditions outside of the transportation and storage conditions, the packaging is damaged, the packaging is opened prior to delivery, or the shock indicator is activated, complete Quality Assurance testing prior to actual use. If the coil passes QA testing, it may be used normally. |

**United States Federal Law**

**Caution**: Federal law restricts this device to sale, distribution, and use by or on the order of a physician. The device is limited by Federal Law to investigational use for indications not in the Indications Statement.

# About This Manual

This manual contains detailed information on the safety precautions, use, and care of this product.

> For safety and accuracy in using the product, read and understand this manual as well as the MRI system user manual and safety manual prior to operation of the product. This manual does not include instructions or safety information on equipment not provided by QED, such as the MRI system. Please consult the MRI system manufacturer for information regarding non-QED equipment.

The operator's manual is available online as a PDF file at www.qualityelectrodynamics.com. To request a paper copy of the operator's manual, please email info@qualedyn.com or complete the contact form at www.qualityelectrodynamics.com.


## Legend

In this manual, the following symbols are used to indicate safety and other important instructions. The signal words and their meanings are defined below.


CAUTION

Caution is necessary to avoid a hazardous situation, which, if not avoided, could result in minor or moderate injury.

INFORMATION

Emphasizes important details or provides information on how to avoid operating errors or other potentially hazardous situation, which, if not observed, may result in property damage.

# Table of Contents

# Chapter 1 – Introduction

## 1.1 Description

Grid Holder CX is used to secure a commercially available biopsy grid or pillar to Breast SPEEDER CX. It consists of biopsy grid holders, a tray, pads, and a plate.

## 1.2 Operating Environment and Compatibility

The Grid Holder CX is intended to be used in conjunction with the Breast SPEEDER CX and Canon 1.5T MRI System in a specialized healthcare facility.

## 1.3 User Profile

Operator – Radiologic technologists, laboratory technologists, physicians.

User training – No special training is required to use this coil. However, Canon Medical Systems provides a comprehensive training course for MRI systems in order to instruct operators on the correct use of MRI systems.

## 1.4 Patient Information

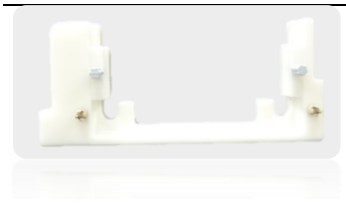
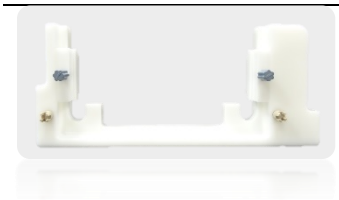
Age, health, condition – No special limitations. Do not use the coil for newborns or infants.

Weight – 255kg or less (consult the operation manual for the MRI system, and if the maximum allowable patient's weight for the system is lower than that for this coil, priority must be given to the maximum weight for the system).

# Chapter 2 – Grid Holder CX Components

## 2.1 Included Components

The Grid Holder CX is shipped with the parts shown below. Upon receipt, please ensure that all parts are included in the shipment. Please contact your Canon Medical Systems representative for replacement or replenishment of any accessories listed here.

| Picture | Description | Quantity | QED Part Number |
|---|---|---|---|
|  | Arm Rest Pad | 1 | 3003078 |
|  | Grid Holder Right* | 1 | 2001191 |
|  | Grid Holder Left* | 1 | 2001190 |
|  | Fluid Tray | 1 | 2001059 |
|  | Blocking Plate | 1 | 2001058 |
|  | Comfort Pad for Blocking Plate | 1 | 3003210 |

*The right and left grid holders are different. Their knobs are color coded to match the color of the knobs on the lateral coil holder.

## 2.2 Compatible Grids

The Grid Holder CX can be used in combination with the biopsy grids listed below. For instructions on using the biopsy grid, consult with the grid manufacturer.


CAUTION

If Grid Holder CX is used in combination with a device not listed in this manual, the device may come off and injury may result.

| Part number | Description | Manufacturer |
|---|---|---|
| 117143* | Grid, Lateral, Re-usable | NORAS MRI products GmbH |
| 112235** | Grid Lateral, Disposable | Medicoplast International GmbH |
| 112238** | Grid Medial, Disposable | Medicoplast International GmbH |
| 111251* | Marker Block for Grid, Re-usable | NORAS MRI Products GmbH |

* Generally available in Europe and USA

**Generally available in Europe

Customers in the US and European countries requiring CE marking may order these products directly from Noras MRI Products GmbH at:

Email: sales@noras.de
Phone: +49(931)29927-0
Fax: +49(931)29927-20

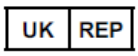
For other countries, please contact Canon Medical Systems Corporation's local subsidiary or distributor for product availability.

# Chapter 3 – Safety

This section describes the general precautions and safety information that must be observed when this coil is used.

> CAUTION Before using the Grid Holder CX, review the safety information in the Breast SPEEDER CX and MRI system operation manuals for a full list of safety considerations.

## 3.1 Symbol Glossary

| Symbol | Number | Standard | Title, Meaning |
|---|---|---|---|
|  | 1641 | ISO 7000<br>IEC 60417 | Operator's manual, Consult operating instructions before operating the device |
|  | 5172 | ISO 7000<br>IEC 60417 | Class II equipment |
|  | 5333 | ISO 7000<br>IEC 60417 | Type BF applied part |
|  | 3082 | ISO 7000<br>IEC 60417 | Manufacturer and Date of Manufacture |
|  | 5.1.2 | ISO 15223-1 | Indicates the Authorized Representative in EU |
|  | 5.1.2 | ISO 15223-1<br>ISO 20417 | Indicates the UK Responsible Person |
|  | 5.1.2 | ISO 15223-1<br>SwissMedic | Indicates the authorized representative in Switzerland |
|  | 2493 | ISO 7000<br>IEC 60417 | Catalog Number |
|  | 2498 | ISO 7000<br>IEC 60417 | Serial Number |
|  | 0632 | ISO 7000<br>IEC 60417 | Temperature limit |
|  | 2620 | ISO 7000<br>IEC 60417 | Humidity limitation |
|  | 2621 | ISO 7000<br>IEC 60417 | Atmospheric pressure limitation |
|  | 5.7.7 | ISO 15223-1 | Medical Device |

| Symbol | Number | Standard | Title, Meaning |
|---|---|---|---|
|  | N/A | EN50419<br>EU2012/18/EU | The use of this symbol indicates that this product should not be treated as household waste.<br>By ensuring that this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product.<br>For more detailed information concerning the return and recycling of this product, please consult the supplier from whom you purchased the product. |
|  | 5.1.8 | ISO 15223-1 | Importer |
|  | 5.1.9 | ISO 15223-1 | Distributor |

## 3.2 Indications

The Grid Holder CX kit is intended for use with the Breast SPEEDER CX to permit access to the breast anatomy for biopsy and lesion localization procedures.

## 3.3 Contraindications

None.

## 3.4 Precautions

None

## 3.5 Cautions

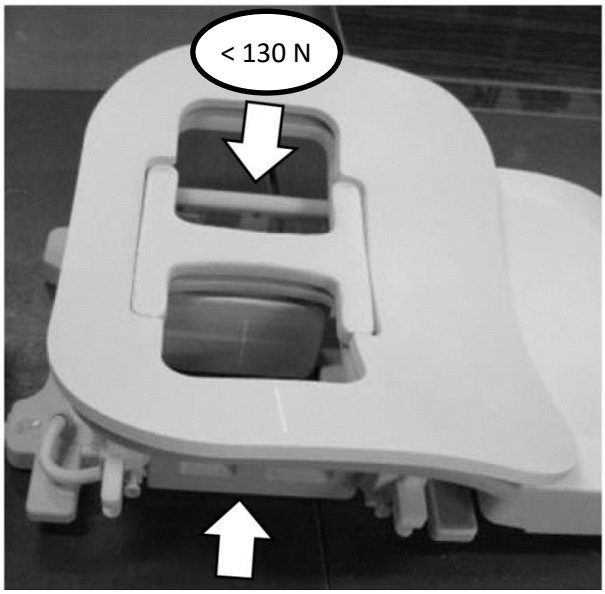
Do not use a defective device, especially if the outer covering has been damaged. This could result in harm to the patient.

Do not attempt to change or modify the device. Unauthorized modifications could result in harm to the patient.

Do not use in conjunction with devices not listed in this manual. The accessory could disconnect and cause injury to the patient.

If the device is found to be defective, stop using the device immediately and contact your Canon Medical Systems representative.

When a biopsy grid is attached to Grid Holder CX, the lateral force applied should not exceed 130 N. If a lateral force of more than 130 N is applied, Grid Holder CX or Breast SPEEDER CX may be damaged or the biopsy grid may shift and patient injury may result.




## 3.6 Emergency Procedures

In case of an emergency during the scan, stop the scan immediately, remove the patient from the room, and obtain medical assistance, if necessary.

If a serious incident occurs in the EU, it should be reported to the manufacturer and the Competent Authority of the Member State in which the user facility is established.

# Chapter 4 – Using the Grid Holder CX

Grid Holder CX is to be used in combination with Breast SPEEDER CX (Canon model MJAM-147A, QED model Q7000125).

| | |
|---|---|
| CAUTION | For safety and accuracy in using this product, please read the Breast SPEEDER CX manual before using Grid Holder CX. |

## 4.1 Using the Grid Holder CX for Lateral Access

Follow the steps below to attach Grid Holder CX at the lateral coil position of Breast SPEEDER CX.

(1) Clean the coil, all parts of the Grid Holder CX, and the biopsy grid before each use. For the cleaning method, refer to Chapter 5.

(2) Place the Breast SPEEDER CX on the couchtop per the instructions in the Breast SPEEDER CX manual.

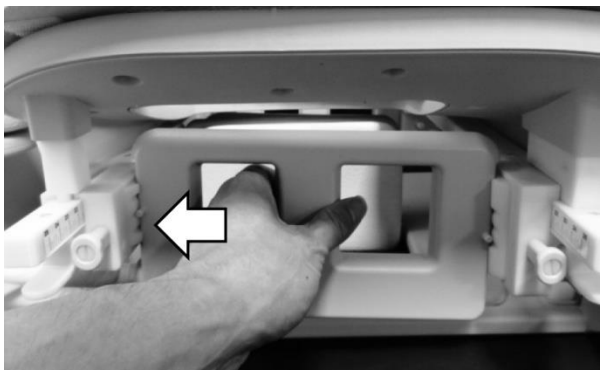
(3) Place the arm rest pad on the couchtop.

**Arm Rest Placement**

(4) Remove the lateral coil from one side of the lateral coil frame. To do this, hold the lateral coil and push it slightly toward the cable exit end. At the same time, pull the opposite end out of the frame as shown below.

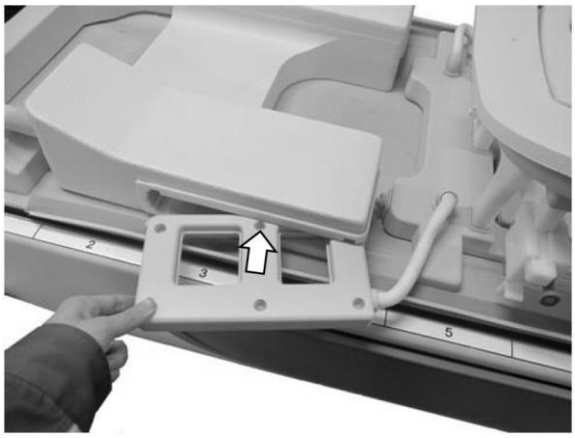
Repeat this procedure for the lateral coil on the other side of the lateral coil frame.

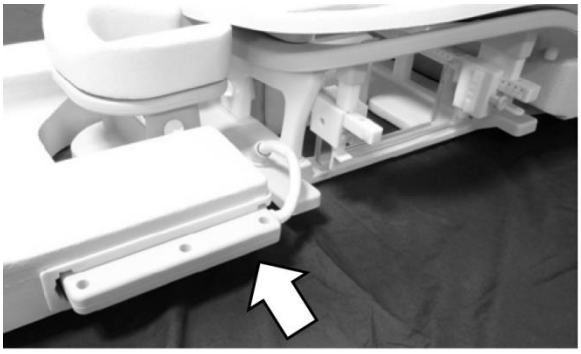
**Remove the Lateral Coil**

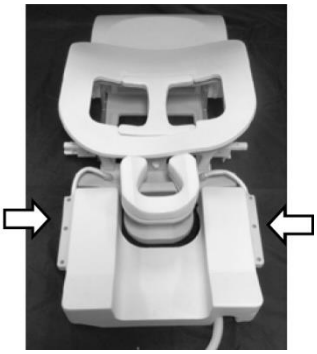


(5) Store each removed lateral coil in the corresponding arm rest pad pocket.

**Store the Lateral Coils**



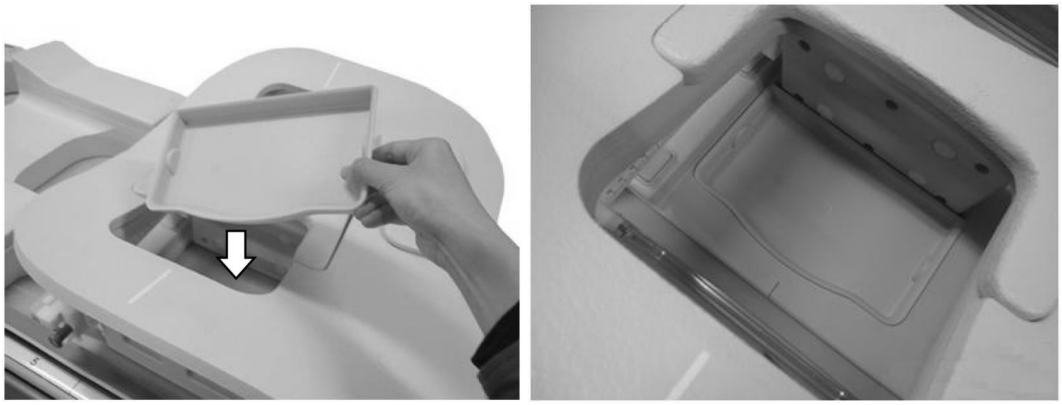


1. When removing the lateral coil, hold the coil gently. Do not use excessive force and do not pull or twist the cable. Failure to observe these precautions may result in contact failure or wire disconnection.


2. When moving the patient into the gantry, confirm that the lateral coils are securely stored in the arm rest pads. If the removed lateral coils are in the gap between the couchtop and the gantry, the lateral coil may be caught by the couchtop during movement.

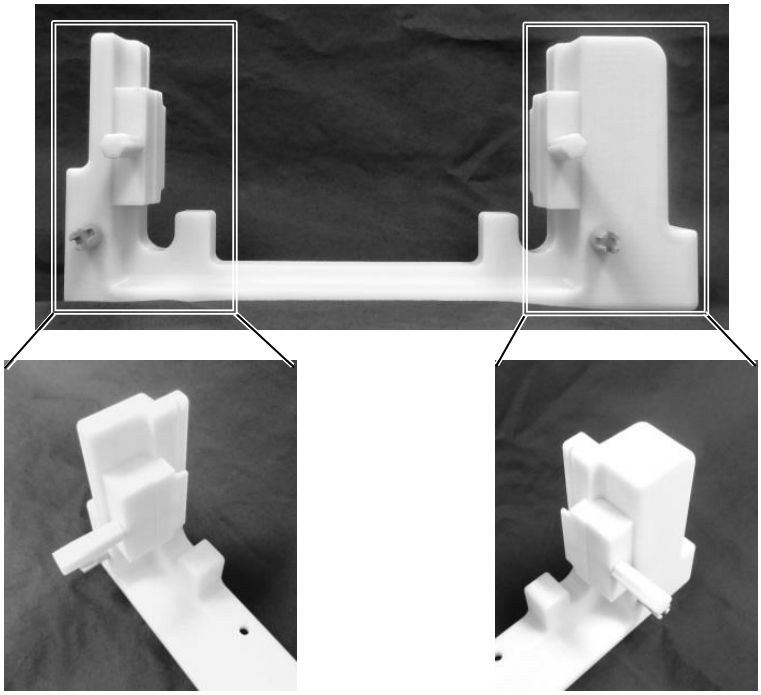
(6) Place the fluid tray in the base of the coil, if necessary.

**Positioning the Fluid Tray**

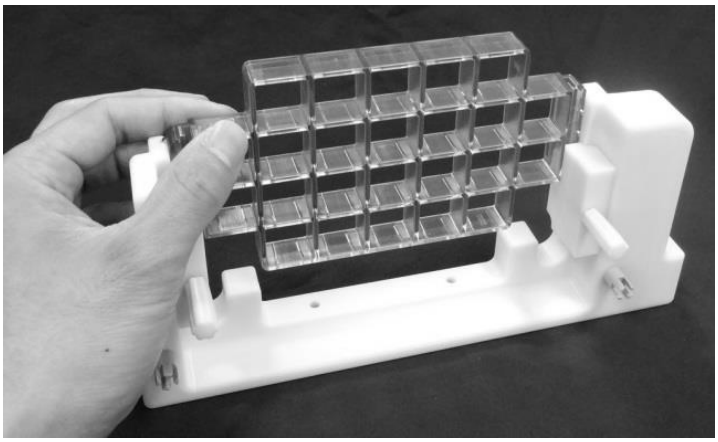


(7) Position the lateral grid (PN 117143 or 112235) in the grid holder as shown below. Orient the grid holder so that the numbers indicated on the scale will be visible from the outside after installation. Slide the grid into the grooves of the grid holder. Secure the grid by rotating the two knobs on the grid holder clockwise until they are fully tightened.

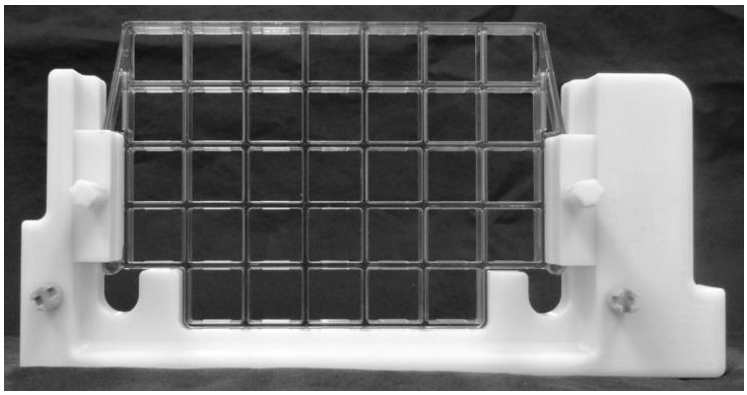
**Locate the Grooves on the Grid Holder**



**Slide the Grid into the Grooves of the Grid Holder**



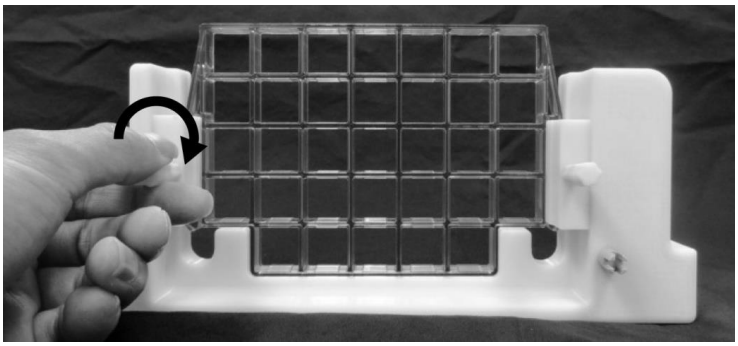
**Grid Holder with Grid in Proper Position**

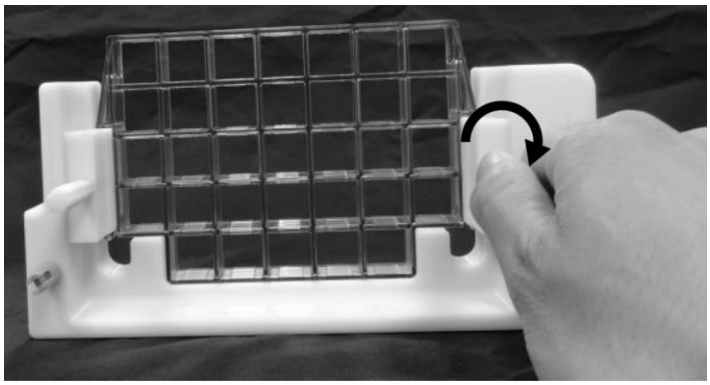


1. Lateral grid part number 112235 is shown in the above photos. Lateral grid part number 117143 can be used in the same way.
2. Confirm that the biopsy grid is oriented correctly. If the biopsy grid is oriented incorrectly, it will not fit into the grid holder.
3. The left and right grid holders are different. Their knobs are color coded to match the knobs on the lateral coil holder.

(8) When the grid is in place, secure it by rotating the two knobs clockwise until they are fully tightened.

**Secure the Grid by Rotating the Knobs**

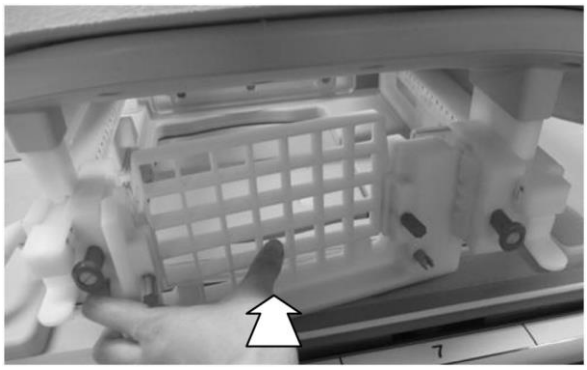


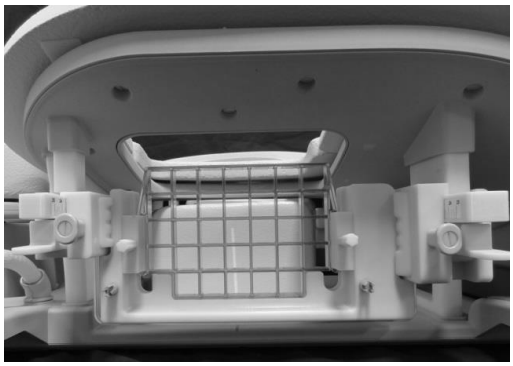


| | |
|---|---|
| CAUTION | After tightening the knobs, confirm that the biopsy grid is immobilized securely. If the grid is not properly attached to the grid holder, the grid may shift during examination and patient injury may result. |

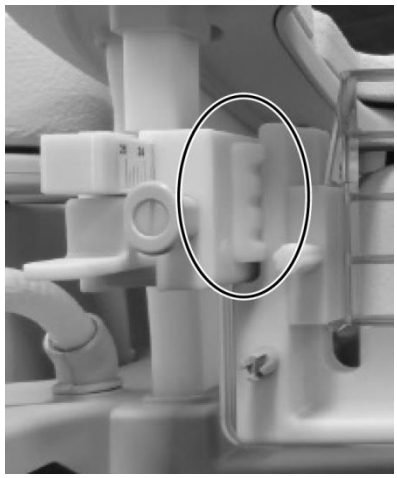
(9) Slide the grid holder with the lateral grid into the lateral coil holder and push in until it clicks. Repeat this for the other side. Visually confirm that the grid holders on both sides are locked in place.

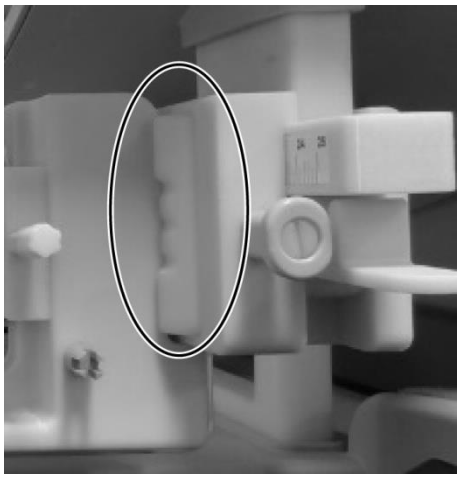
**Slide the Grid Holder into the Lateral Coil Holder and Push Until it Clicks**





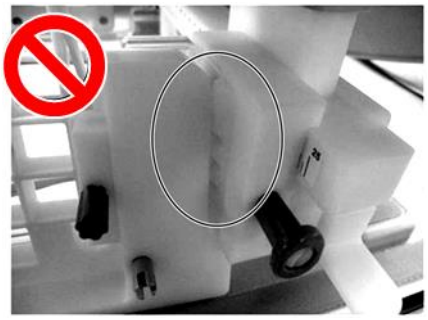
**Confirm that the Grid Holders are Locked in Place**



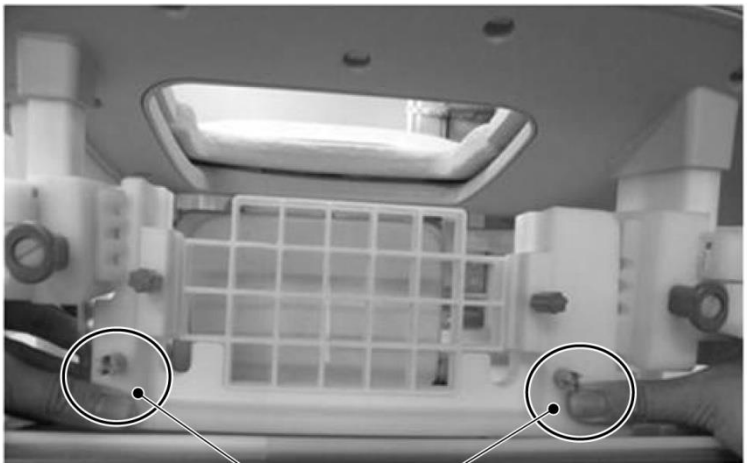


CAUTION

Be sure to push the grid holder until it clicks. If the grid and grid holder are not securely locked in place, it may come off unexpectedly and injury may result.



Push the bottom of the grid holder to ensure it is attached securely.



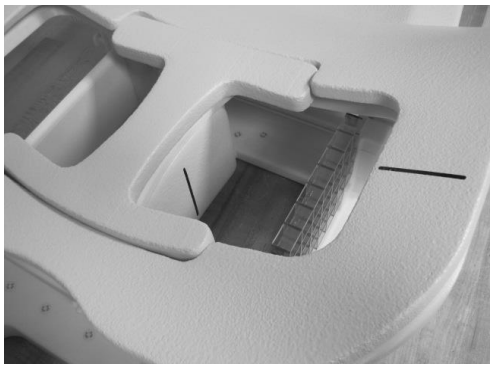
**Push**

If it is necessary to remove the grid holder in order to reposition it, refer to the instructions on removing the grid in Section 4.4.

(10) If required, adjust the horizontal position of the lateral coil holder using a ruler as a guide. Refer to the Breast SPEEDER CX Operator's manual.

(11) The Grid Holder CX is now ready for lateral imaging and/or biopsy. Refer to the Breast SPEEDER CX and MRI system user manuals for instructions on patient positioning and scanning.

**Lateral Access Set-Up**



| | |
|---|---|
| CAUTION | When positioning the patient, ensure patient's weight is not applied to the biopsy grid from above. The grid may shift during examination and patient injury may result. |

| | |
|---|---|
| i | Choose "BreastCX LatA Bilat" or "BreastCX DualA Bilat" as the coil type for the MRI scan. If another coil type is chosen, the image quality may deteriorate. |

(12) For instructions on using the biopsy grid and biopsy needles, refer to the manual provided by the manufacturer.

## 4.2 Using the Grid Holder CX for Medial Access

Follow the steps below to attach Grid Holder CX at the lateral coil position of Breast SPEEDER CX.

(1) Clean the coil, all parts of Grid Holder CX, and the biopsy grid before each use. For the cleaning method, refer to the Chapter 5.

(2) Place the Breast SPEEDER CX on the couchtop per the instructions in the Breast SPEEDER CX manual.

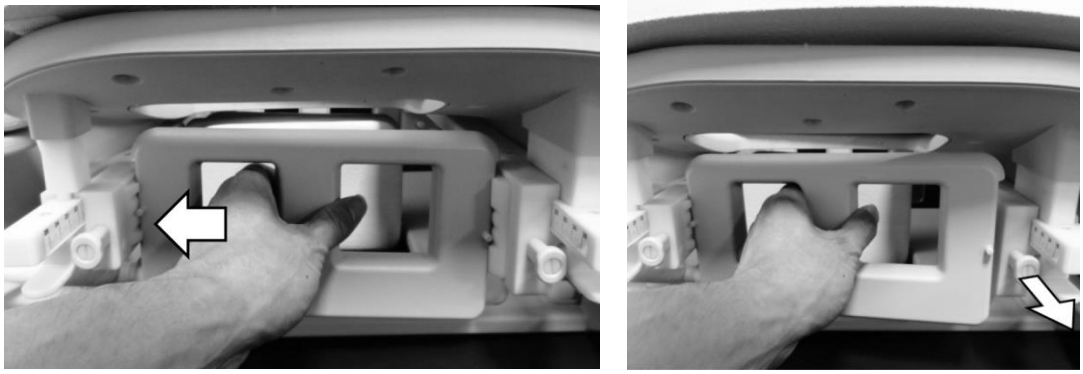
(3) Place the arm rest pad on the couchtop.

**Arm Rest Placement**

(4) Install the compression plate on the side where the biopsy is to be performed. Refer to the operation manual for Breast SPEEDER CX.

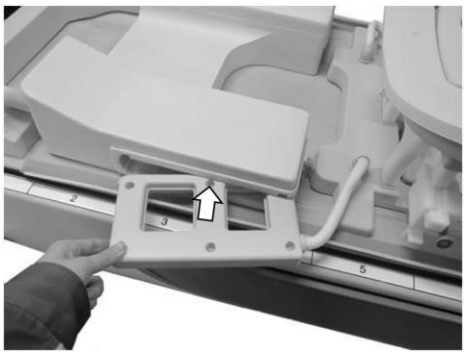
(5) Remove the lateral coil from the lateral coil holder on the side that is <u>not</u> being imaged. To do this, hold the lateral coil and push it slightly toward the cable exit end. At the same time, pull the opposite end out of the frame as shown below.

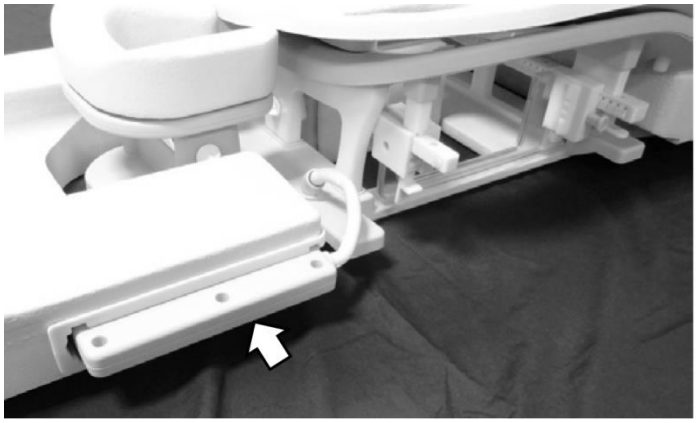
**Remove the Lateral Coil**

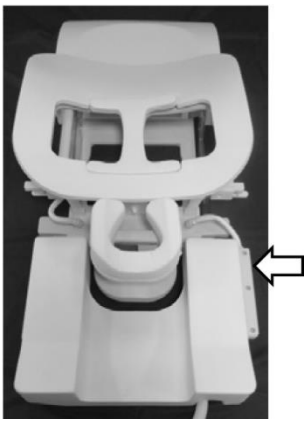


(6) Store the removed lateral coil in the corresponding arm rest pad pocket.

**Store the Lateral Coils**





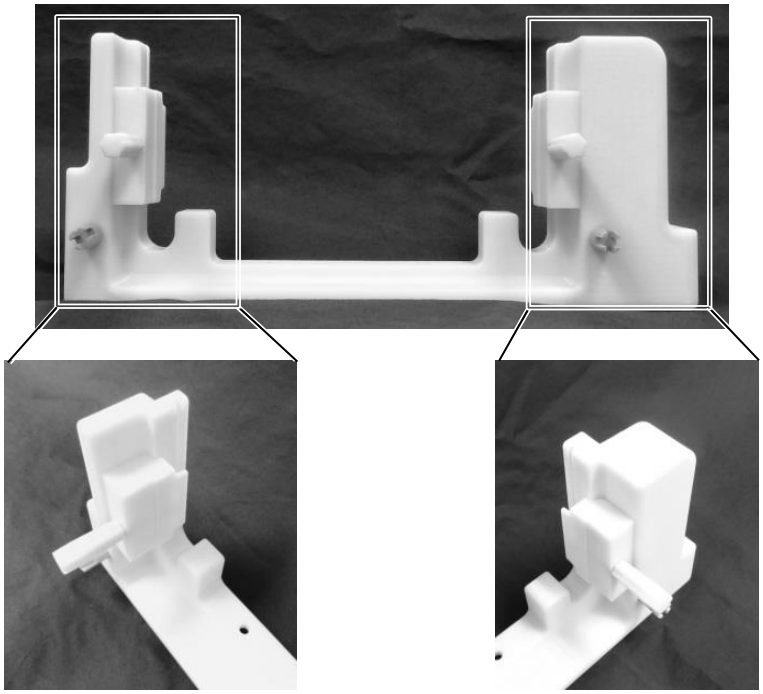


1. When removing the lateral coil, hold the coil gently. Do not use excessive force and do not pull or twist the cable. Failure to observe these precautions may result in contact failure or wire disconnection.

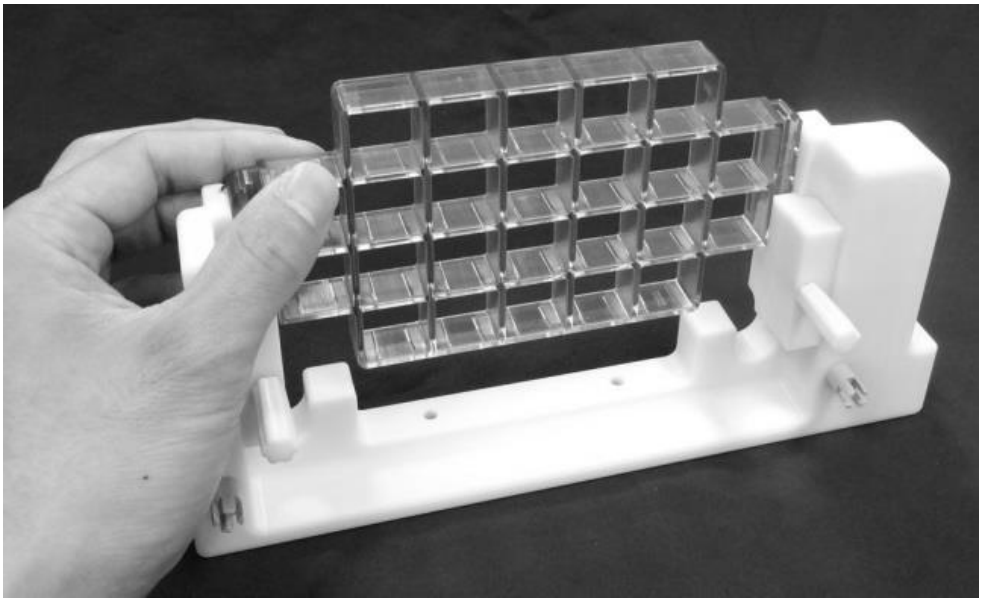
2. When moving the patient into the gantry, confirm that the lateral coils are securely stored in the arm rest pads. If the removed lateral coils are in the gap between the couchtop and the gantry, the lateral coil may be caught by the couchtop during movement.

(7) Position the medial grid (PN 112238) in the grid holder as shown below. Orient the grid holder so that the numbers indicated on the scale will be visible from the outside after installation. Slide the grid into the grooves of the grid holder. Secure the grid by rotating the two knobs on the grid holder clockwise until they are fully tightened.

**Locate the Grooves on the Grid Holder**



**Slide the Grid into the Grooves of the Grid Holder**

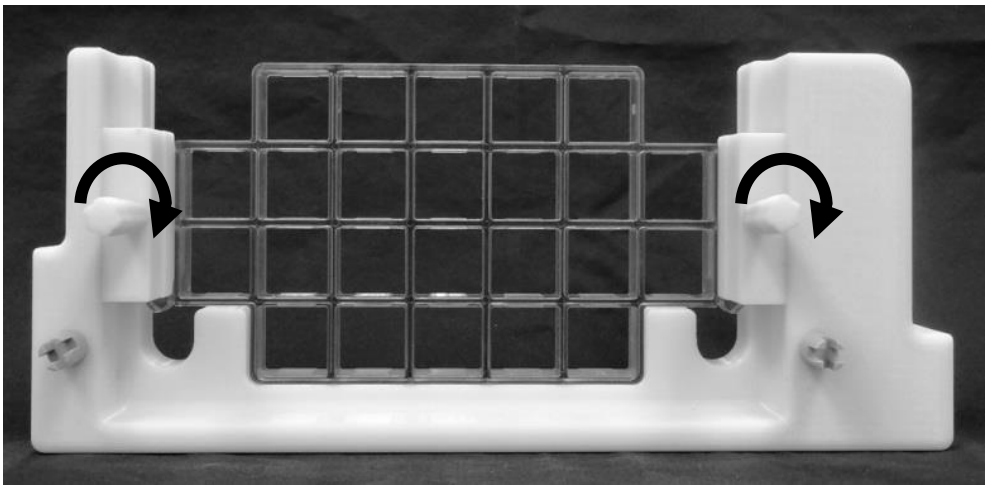


1. Confirm that the biopsy grid is oriented correctly. If the biopsy grid is oriented incorrectly, it will not fit into the grid holder.

2. The left and right grid holders are different. Their knobs are color coded to match the knobs on the lateral coil holder.

(8) When the grid is in place, secure it by rotating the two knobs clockwise until they are fully tightened.

**Secure the Grid by Rotating the Knobs**

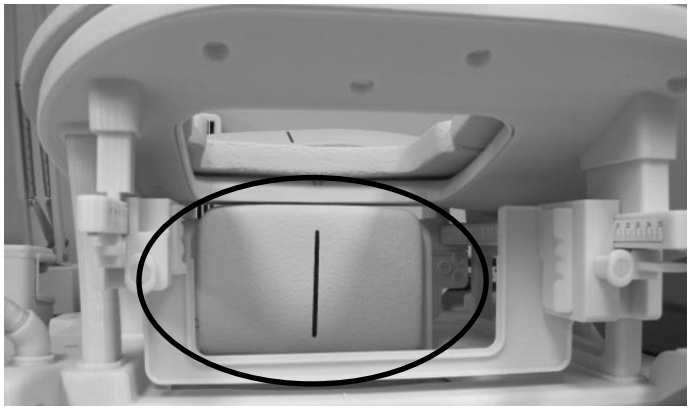


CAUTION

After tightening the knobs, confirm that the biopsy grid is immobilized securely. If the grid is not properly attached to the grid holder, the grid may shift during examination and patient injury may result.

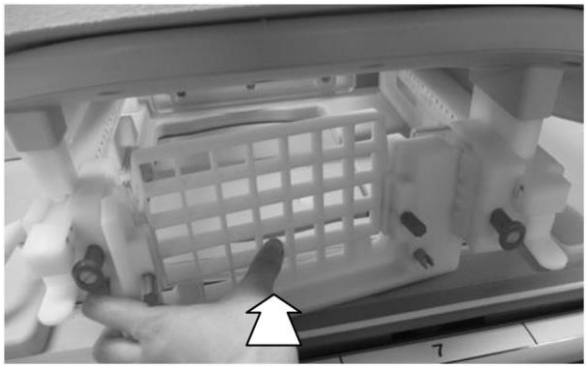
(9) Remove the medial pads from both sides of the medial coil.

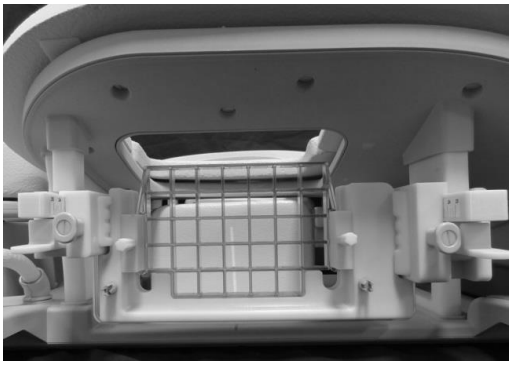
**Medial Pads**



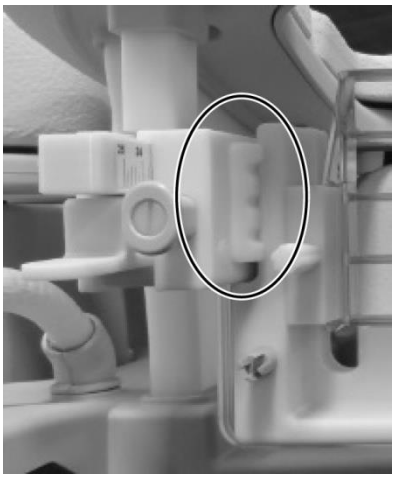
(13) Slide the grid holder with the medial grid into the lateral coil holder and push in until it clicks. Repeat this for the other side. Visually confirm that the grid holders on both sides are locked in place.

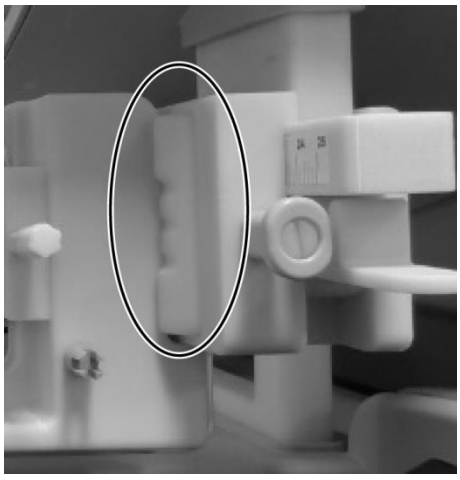
**Slide the Grid Holder into the Lateral Coil Holder and Push Until it Clicks**





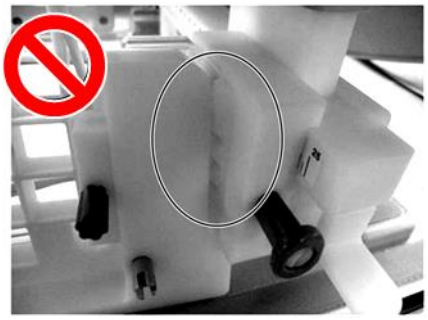
**Confirm that the Grid Holders are Locked in Place**



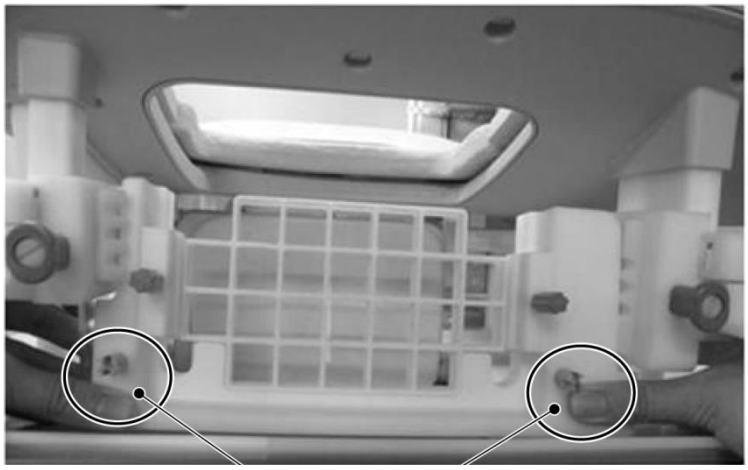


CAUTION

Be sure to push the grid holder until it clicks. If the grid and grid holder are not securely locked in place, it may come off unexpectedly and injury may result.



Push the bottom of the grid holder to ensure it is attached securely.

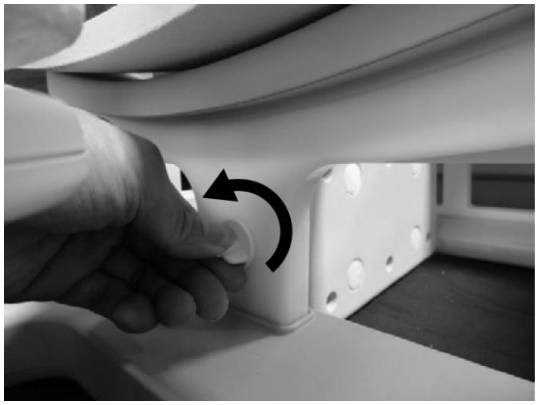


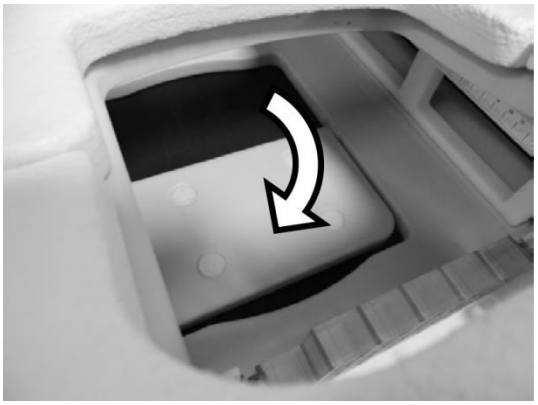
**Push**

If it is necessary to remove the grid holder in order to reposition it, refer to the instructions on removing the grid in Section 4.4.

(10) Unlock the medial coil by rotating the knob counterclockwise. Flip the medial coil down on the side that is not being imaged.

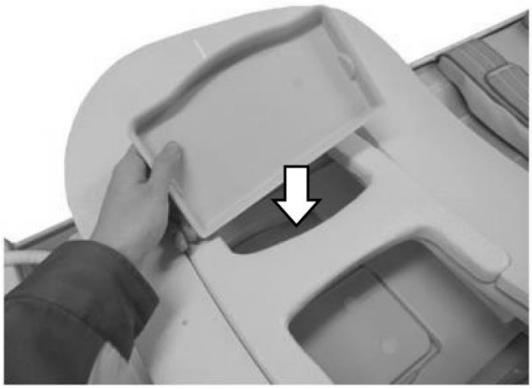
**Move the Medial Coil**





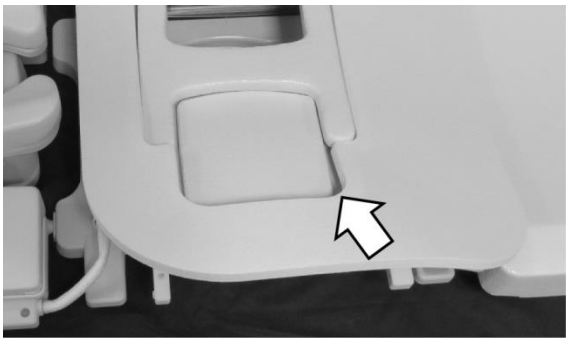
(11) Set the fluid tray in the base of the coil if necessary.

**Position Fluid Tray**



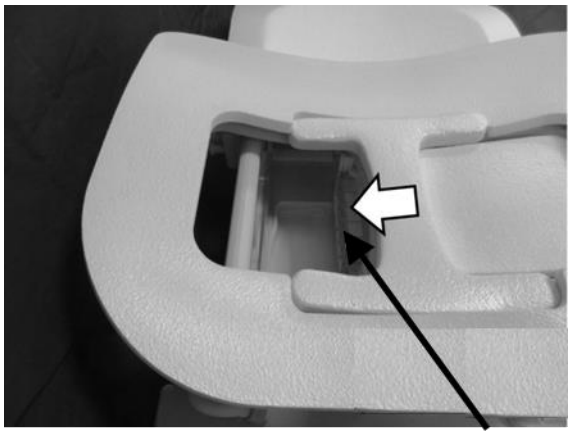
(12) If the breast that is not being imaged interferes with the imaging, place a blocking plate with comfort pad in the opening for this breast.

**Positioning Blocking Plate and Pad**



(13) Unlock the lateral coil holder and move it across the center of the coil. Refer to the operation manual for Breast SPEEDER CX for details.

**Move the Grid Holder Across the Center of the Coil**



(14) The Grid Holder CX is now ready for medial imaging and/or biopsy. Refer to the Breast SPEEDER CX and MRI system user manuals for instructions on patient positioning and scanning.

| | |
|---|---|
| CAUTION | When positioning the patient, ensure patient's weight is not applied to the biopsy grid from above. The grid may shift during examination and patient injury may result. |

| | |
|---|---|
| i | Choose "BreastCX LatA Bilat" or "BreastCX DualA Bilat" as the coil type for the MRI scan. If another coil type is chosen, the image quality may deteriorate. |

(15) For instructions on using the biopsy grid and biopsy needles, refer to the manual provided by the manufacturer.

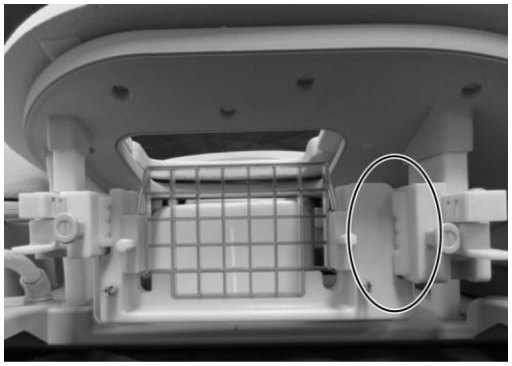
## 4.3 Patient Positioning and Scanning

For the patient positioning and image acquisition procedures, refer to the operation manual for Breast SPEEDER CX (MJAM-147A).

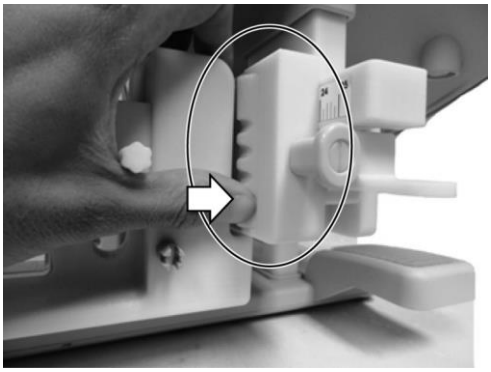
## 4.4 Removing the Grid Holder

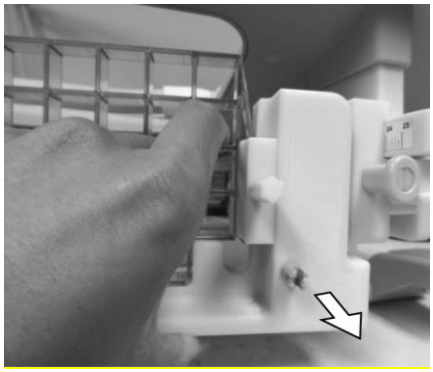
(1) Push the spring-loaded bracket at the foot end and move the grid holder outward as shown below.

**Spring-Loaded Bracket**



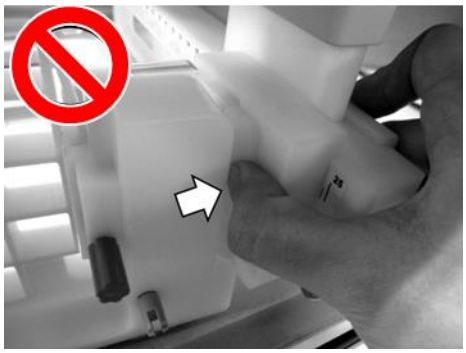
**Push In the Spring-Loaded Bracket and Pull Outward**





CAUTION

Be careful not to pinch a finger when removing the grid holder. Fingers may be injured if they are caught between the frame and the grid holder.



# Chapter 5 – Cleaning, Maintenance, Service, and Disposal

## 5.1 Cleaning of the Grid Holder CX

CAUTION

1. Do not pour cleaning solution directly onto the Grid Holder CX.
2. Do not sterilize the product by subjecting it to a high temperature or by exposing it to ethylene oxide gas. The resin parts may become deformed.
3. Do not use benzine to clean the product. This may result in discoloration, distortion, deterioration, or damage.

All parts of the Grid Holder CX should be cleaned after each use using the following procedure.

Disassemble the Grid Holder CX into its individual components prior to cleaning.

1. Wipe off any dirt on the coil surface using a dry cloth. If dirt is difficult to remove, clean it according to the procedures described below.
2. Wipe with a cloth or gauze that has been dampened with 70-99% isopropanol, 70% ethanol, mild detergent diluted with water, or water.
3. Allow the coil to dry completely, preferably for a full day.
4. Dispose of any materials used to clean the coil and the pads according to all federal, state, and local regulations.
5. Commonly available cleaning agents can also be used on the surface of the coils without compromising the safety of the device. Refer to the cleaning agent manufacturer's instructions for use and clean the coil according to the procedures specified by the healthcare facility.

Some cleaning agents may cause discoloration. This does not affect proper functioning.

## 5.2 Cleaning, Disinfection, and Sterilization of Reusable Biopsy Grid

The reusable biopsy grid (117143) and marker block (111251) require initial treatment before use per the procedure below.

Disposable biopsy grids (112235 and 112238) are delivered sterile and require no pre-treatment. Dispose of the grids immediately after use; do not re-use.

Use detergents and disinfectants approved by the Verbund für Angewandte Hygiene e.V (VAH) or the Robert Koch Institute (RKI). The VAH list can be found online at https://vah-online.de/en/vah-list. The RKI list can also be found online at https://www.rki.de/EN/Home/homepage_node.html;jsessionid=DD4C548C3376284EB1A6F87AB3945FCF.internet101.

In addition, follow the guidelines of the Centers for Disease Control (CDC) in the Anglo-American area, which can be found at https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html.

All steps of this cleaning, disinfection and sterilization procedure have been validated with the detergents and disinfectants specified in the procedure and are recommended by the biopsy grid and marker block manufacturer, NORAS MRI Products GmbH. If the user deviates from these instructions, the user is responsible for selecting suitable alternative cleaning and disinfection agents and validating the processes.

1. Frequent processing can have an impact on these products (color changes), but do not affect the function of the product.
2. Always wear protective gloves and comply with the application times for Hepatitis B and HI viruses (see the instructions for use of the respective disinfectant solution).

### 5.2.1 Manual Pre-Cleaning

The described procedure is qualified on the basis of the guideline for manual cleaning and disinfection (DGKH, DGSV, AKI and VAH 2013) and the standard DIN EN ISO 15883 part 1 and part 5.

| Process Step | Time / Temperature | Comment on the Process Step |
|---|---|---|
| **Manual Cleaning** | | |
| • Rinse the contaminated medical devices under running cold water<br>• Cavities are cleaned with a soft brush. | 2 min / < 25 °C (cold water) | Use of tap water |
| • Soak the instruments in a freshly prepared cleaning solution.<br>• Hand wash the instruments in a fresh cleaning solution. Coarse dirt is removed with a soft brush.<br>• Rinse the cavities (5x) with an unused disposable syringe. A minimum volume of 20 ml is required. | 5 min / < 25 °C (cold water) | Process chemical used: 1.5% Dr. Weigert - "Medi Clean forte" |

| Process Step | Time / Temperature | Comment on the Process Step |
|---|---|---|
| Cleaning in an ultrasonic bath | 15 min / < 25 °C (cold water) | Process chemical used: 1.5% Dr. Weigert - "Medi Clean forte" |
| • Rinse the medical devices under running water.<br>• Rinse the cavities (3x) with an unused disposable syringe. A minimum volume of 20 ml is required. | 1 min / < 25 °C (cold water) | Use of demineralised water |
| • Visual inspection - Repeat the previous steps until there is no more visible contamination. | --- | --- |
| Thorough rinsing with water | 1 min / < 25 °C (cold water) | Use of demineralised water |
| Drying | --- | Residual moisture can be completely removed. |
| **Manual Disinfection** | | |
| • Insert the cleaned medical products into the disinfectant solution.<br>• Rinse the cavities (2x) with an unused disposable syringe at the beginning and end of the reaction time. A minimum volume of 20 ml is required. | 10 min / < 25 °C (cold water) | Process chemical used:<br>Paul Hartmann AG - 0.75% Korsolex med AF |
| • Rinse medical devices under running cold water<br>• Rinse the cavities (5x) with an unused disposable syringe. A minimum volume of 20 ml is required. | 1 min / < 25 °C (cold water) | Use demineralised water |

**Procedure for Manual Cleaning and Disinfection (Wipe Disinfection)**

| Process Step | Time / Temperature | Comment on the Process Step |
|---|---|---|
| **Manual Cleaning/ Disinfection** | | |
| Wetting of contaminated medical devices with Bacillol® 30 Foam. | 30 s / < 25 °C | Use of the process chemical Paul Hartmann AG - "Bacillol® 30 Foam |
| Wipe off contaminated medical products with a cloth moistened with Bacillol® 30 Foam until all visible soiling has been removed. | 30 s / < 25 °C | Use of the process chemical Paul Hartmann AG - "Bacillol® 30 Foam |
| Drying by wiping with a lint-free cloth. | --- | --- |
| Repeat the process until all visible soiling has been removed. | --- | --- |

### 5.2.2 Automatic Cleaning and Disinfection

The described procedure is qualified on the basis of the guideline for automatic cleaning and disinfection (DGKH, DGSV and AKI 2017) and the standard DIN EN ISO 15883 part 1 and part 5.

| Process Step | Time / Temperature | Comment on the Process Step |
|---|---|---|
| **Manual pre-cleaning** | | |
| • Rinse the contaminated medical products under running cold water until all visible contamination has been removed.<br>• Cavities are cleaned with a soft brush<br>• Rinse the cavities (5x) with an unused disposable syringe. | 3 min / < 25 °C (cold water) | Use tap water |
| Cleaning in an ultrasonic bath | 10 min / < 25 °C (cold water) | Process chemical used: 1.5% Dr. Weigert - "MediClean forte" |

| Process Step | Time / Temperature | Comment on the Process Step |
|---|---|---|
| **Automatic cleaning and disinfection** | | |
| Pre-cleaning | 2 min / < 25 °C (cold water) | Use of tap water |
| Cleaning | 10 min / 55 °C | Process chemical used: 0.5% Dr. Wei-gert - "MediClean forte" |
| Intermediate rinsing | 2 min / < 25 °C (cold water) | Use of tap water |
| Neutralisation | 1 min / < 25 °C (cold water) | Process chemical used: 0.1% Dr. Wei-gert - "Neodisher Z" |
| Disinfection | 5 min / 93 °C | Use of tap water |
| Drying | 10 min / < 90 °C | --- |

Automatic disinfection is preferable to manual disinfection.

### 5.2.3 Disinfecting Washing Process

The described procedure was carried out based on the recommendation of the disinfectant commission of the VAH for laundry disinfection.

| Process step | Time / Temperature | Comment on the Process Step |
|---|---|---|
| Wash | 130 min / 95 °C | Use tab water<br>Process chemical used:<br>Heavy duty detergent:<br>Persil Duo Caps |

### 5.2.4 Sterilization

The described procedure was qualified on the basis of the standard DIN EN ISO 11138-3 and EN 285.

| Process Step | Time / Temperature | Comment on the Process Step |
|---|---|---|
| Sterilization | 5 min / 134 °C | sterilization in saturated steam with fractionated vacuum |
| Drying | 20 min / < 134 °C | --- |

This sterilization cycle is not considered by the US FDA to be a standard sterilization cycle. Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization

containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).

## 5.3 Maintenance

No regularly scheduled maintenance is required for the Grid Holder CX.

## 5.4 Service

Please contact your Canon Medical Systems representative with questions regarding service of the Grid Holder CX.

## 5.5 Disposal

Please follow local regulations for the disposal of electrical equipment. Do not dispose of the Grid Holder CX in unsorted waste bins. Contact your Canon Medical Systems representative with questions regarding the return or disposal of the Grid Holder CX.

## 5.6 Expected Service Life

This product is designed for an expected service life of at least 6 years under normal usage conditions. The product is safe to use beyond the expected service life as long as information in the Safety section is followed the product continues to function as expected.

CE 2797

UK CA 0086

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