SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)

MammoMark® Biopsy Site Identifier
CorMARK® Biopsy Site Identifier

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Summary of safety and performance for patients/lay person

This Summary of Safety and Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of the safety and performance prepared for healthcare professionals is found in the first part of this document, section A.

The SSCP is not intended to give general advice on the diagnosis and/or treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. The SSCP is not intended to replace the Instructions For Use to provide information the safe use of the device.

1.0 DEVICE IDENTIFICATION AND GENERAL INFORMATION

1.1 Device Trade Name(s)

- MammoMARK® Biopsy Site Identifier
- CorMARK® Biopsy Site Identifier

1.2 Manufacturer's Name and Address

Legal Manufacturer:
Devicor Medical Products, Inc.
300 E-Business Way, Fifth Floor
Cincinnati, OH 45241
USA

Manufacturing Site:
Devicor Medical Products de Mexico S de R.L. de C.V
Parque Industrial Chilpancingo
Sor Juana Ines De La Cruz 20152
4-B, CP 22440 Tijuana, B.C., MEXICO

1.3 Basic UDI-DI

Table 1: Basic UDI-DI Numbers

Products	Basic UDI-DI #
MAM3001, MAM3002, and MAM3008	08419111IAOA04000003322LP
MRM4002, and MRM4008	08419111IAOB04000003322MU
MMK0801, MMK0802, MMK1001, and MMK1002	08419111IAOC04000003322NZ
MAM3014	08419111IAOD04000003322Q6

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1.4 Risk class of device

The products are classified as Class III, non-active implantable devices per the Medical Device Regulation (EU) 2017/745.

1.5 Year when the device was first CE-marked under Regulation EU 2017/745

The MammoMARK® Biopsy Site Identifier and CorMARK® Biopsy Site Identifier devices are currently undergoing review to meet compliance with Regulation (EU) 2017/745.

The MammoMARK® Biopsy Site Identifier and CorMARK® Biopsy Site Identifier devices have been on the European Market with a CE mark since 2006.

2.0 INTENDED USE OF THE DEVICE

2.1 Intended purpose

MMK0801, MMK0802, MMK1001, MMK1002:

The MammoMARK® Biopsy Site Identifier is intended for use after an open surgical or percutaneous breast biopsy procedure to mark the biopsy site.

MAM3008, MRM4008, MAM3001, MAM3002, MRM4002, MAM3014:

The MammoMARK® Biopsy Site Identifier and the CorMARK® Biopsy Site Identifier are intended for use after an open surgical or percutaneous breast biopsy procedure to mark the biopsy site.

2.2 Indications and intended patient groups

MMK0801, MMK0802, MMK1001, MMK1002:

The MammoMARK® Biopsy Site Identifier is intended for use after an open surgical or percutaneous breast biopsy procedure to mark the biopsy site.

MAM3008, MRM4008, MAM3001, MAM3002, MRM4002, MAM3014:

The MammoMARK® Biopsy Site Identifier and the CorMARK® Biopsy Site Identifier are intended for use after an open surgical or percutaneous breast biopsy procedure to mark the biopsy site.

2.3 Contraindications

- Do not implant in infected areas.
- Do not use on patients with known allergies to bovine and/or collagen products.

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3.0 DEVICE DESCRIPTION

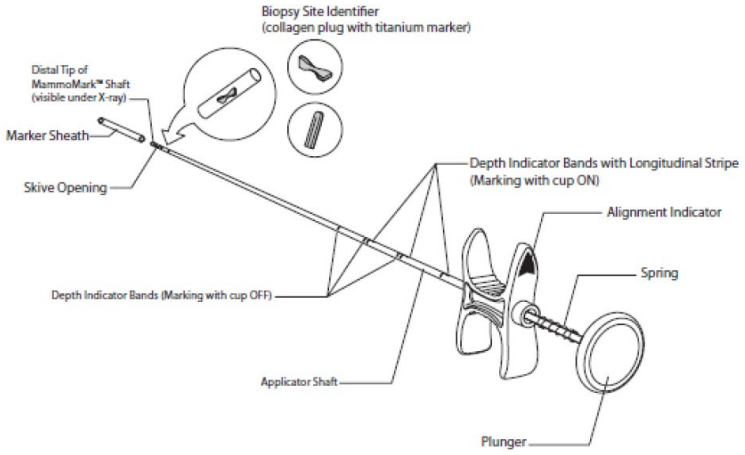
3.1 General Device Description

The MammoMARK® Biopsy Site Identifier(s) and CorMARK® Biopsy Site Identifier are surgical markers, which are detectable by ultrasound, x-ray and magnetic resonance (MR) imaging giving clinicians the ability to identify a biopsy site.

The device consists of two portions.

- An absorbable expanding collagen plug with a permanent marker that can be placed in the body, and
- A syringe like applicator to place the collagen plug/marker in the desired location.

MammoMARK® Biopsy Site Identifier(s) and CorMARK® Biopsy Site Identifier are intended for single use and are supplied sterile and preloaded with a disposable applicator.



Device Models: MMK0801, MMK0802, MMK1001, MMK1002:
The MammoMARK® Biopsy Site Identifiers are made of a absorbable collagen material made of two type 1 collagens and embedded with a permanent titanium marker. Each MammoMARK® Site Identifier is packaged sterile in a flexible, disposable applicator for single patient use.

The MammoMARK® Biopsy Site Identifiers identified above are designed for use with Mammotome Revolve™ Biopsy Probes. At the completion of a breast biopsy procedure, the collagen plug is deployed into the biopsy site through the biopsy probe. After deployment, a spring retracts the plunger, leaving the collagen plug and marker in place.

At the completion of a breast biopsy procedure, the collagen plug is deployed into the biopsy cavity using the applicator. Because of its absorbent characteristics, the collagen material swells within the

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biopsy cavity when infused with tissue fluids. The collagen is slowly absorbed, and the marker is left behind as the permanent indicator of the biopsy site. Once placed, the different shaped markers allow the physician to distinguish between biopsy sites for patients who require multiple biopsies in the same breast. The collagen plug of the biopsy site identifier is temporarily visible on ultrasound. Absorption of the collagen is complete at 30-60 days, with no visibility under x-ray and MRI imaging. The titanium marker remains in place permanently and is visible under x-ray and MRI imaging. To facilitate proper evaluation of subsequent biopsies, the pathologist should be made aware of the presence of the biopsy site identifier in the biopsy site.
MRI Information:

Testing has demonstrated the permanent marker of the biopsy site identifier of the MammoMARK® devices are **MR Conditional**. It is safe to have MRI Imaging per the conditions defined within product instructions for use.

Device Models: MAM3008, MRM4008, MAM3001, MAM3002, MRM4002, MAM3014:

The MammoMARK® Biopsy Site Identifiers are made of an absorbable collagen material made of two type 1 collagens embedded with a permanent titanium marker. Each MammoMARK® site identifier is packaged sterile in a flexible, disposable applicator for single patient use.

The MammoMARK® devices identified above are designed for use with biopsy probes such as the Mammotome® probes and targeting sets. At the completion of a breast biopsy procedure, the collagen plug is deployed into the biopsy site through the biopsy probe or targeting device. After deployment, a spring retracts the plunger, leaving the collagen plug and marker in place.

The CorMARK® Biopsy Site Identifier is an absorbable collagen material made of two type 1 collagens and embedded with a permanent titanium marker. The CorMARK® site identifier is packaged sterile in a rigid disposable applicator for single patient use.

Because of its absorbent characteristics, the collagen plug swells within the biopsy cavity when infused with tissue fluids. The collagen is slowly absorbed, and x-ray visible marker is left behind as the permanent indicator of the biopsy site. Once placed, the differently shaped markers allow the physician to distinguish between different biopsy sites for patients who require multiple biopsies in the same breast. The collagen plug of the biopsy site identifier is temporarily visible on ultrasound. Absorption of the collagen is complete at 30-60 days, with no visibility under x-ray and MRI imaging. The titanium marker remains in place permanently and is visible under x-ray and MRI imaging. To facilitate proper evaluation of subsequent biopsies, the pathologist should be made aware of the presence of the biopsy site identifier in the biopsy site.
MRI Information:

Testing has demonstrated the permanent marker of the biopsy site identifier of the MammoMARK® devices and the CorMARK® device are **MR Conditional**. It is safe to have MRI Imaging per the conditions defined within product instructions for use.

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3.2 Information about medicinal substances in the device

Not applicable, the device does not contain medicinal substances.

3.3 Description of how the device is achieving its intended mode of action

The MammoMARK® Biopsy Site Identifier(s) and CorMARK® Biopsy Site Identifier are surgical markers, which are detectable by ultrasound, x-ray and magnetic resonance (MR) imaging giving physicians the ability to identify a biopsy site.

The device consists of two portions.

- An absorbable expanding collagen plug with a permanent marker that can be placed in the body, and
- A syringe like applicator to place the collagen plug/marker in the desired location.

The MammoMARK® Biopsy Site Identifier and the CorMARK® Biopsy Site Identifier are intended for use after an open surgical or breast biopsy procedure to mark the biopsy site.

3.4 Description of accessories, if any.

No Accessories are included with the device

4.0 RISKS AND WARNINGS

Contact your healthcare professional if you are concerned about the use of the device or about the results. This document is not intended to replace a consultation with your healthcare professional, if needed.

4.1 How potential risks have been controlled or managed

Medical device manufacturers are required to control and manage device risks. All risks are mitigated as far as possible. Any remaining risks and undesirable effects are communicated through contraindications, warnings, precautions, and adverse reactions.

4.2 Remaining risks and undesirable effects

The remaining risks and, although rare, potential adverse reactions and undesirable effects for the patient include the following:

- Foreign Body Reaction – The implanted portion of the biopsy site identifer has a risk of causing reaction in which the body forms a physical barrier to isolate it from the body and becomes inflammed.
- Hypersensitivity – The implanted portion of the biopsy site identifer has a risk of causing an immunlogic response (allgeric reaction) if there is an unknown allergy to the materials implanted.

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- Infection – The biopsy site has a risk of infection (from bacteria, fungi, virus) due to the surgery. Infections may cause redness, delayed healing, pain, tenderness, swelling.
- Marker Migration – The biopsy site identifier (marker) has risk of movement after it is deployed to the biopsy site.

If you are experiencing symptoms or undesirable effects, contact your healthcare professional.

4.3 Warnings and precautions

Contact your healthcare professional if you are experiencing any symptoms mentioned in section 4.2 and are concerned about any adverse reactions or undesireable effects of the device. This document is not intended to replace a consultation with your healthcare professional, if needed.

The warnings and precautions provided within the device's instructions for use are specific to the healthcare professional and don't include actions or measures the patient should take. The device instructions for use, which contain the warnings and precautions could be found at the following website: [link]www.mammotome.com/ifu-index

4.4 Summary of any field safety corrective actions including field safety notices, if applicable.

There are no field safety corrective actions including field safety notices for the MammoMARK® Biopsy Site Identifier devices or CorMARK® Biopsy Site Identifier.

5.0 SUMMARY OF CLINICAL EVALUATION AND POST-MARKET PERFORMANCE FOLLOW_UP

5.1 Clinical Background of the Device

Breast cancer is the most common female cancer affecting more than one in ten women. When abnormalities are detected during screening, timely and non-operative diagnosis is recommended. The standard of care is the "triple assessment" involving:

- imaging (usually mammography and ultrasound)
- clinical examination
- image-guided biopsy for histological examination-Percutaneous biopsy

Percutaneous breast biopsy (through the skin) approaches have emerged as standard of care in the last two decades for the diagnosis of palpable and nonpalpable breast lesions. These minimally invasive biopsies provide many advantages in terms of cost, complications, time, invasiveness, recovery, and cosmetic procedure compared to open surgical biopsies. These procedures are performed by a person trained for image-guided breast biopsy such as a radiologist, a radiographic practitioner or breast clinician.
Metal markers were developed in the early to mid-1990s to mark the location where a biopsy occurred. When the legion is benign, the marker remains in the body and is used

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for future screening. When the lesion is diagnosed as malignant, the marker is used in helping guide the physician to the location of the tumor and may be removed through treatment.

5.2 The Clinical Evidence for CE marking

There were no clinical investigations performed with the devices under evaluation prior to their market release.
Since placing the product on the European market, a post market clinical follow-up study has been performed by Devicor Medical Products, Inc to characterize the safety and performance of MammoMARK® Biopsy Site Identifier and CorMARK® Biopsy Site Identifier.
The study was conducted using ethical principles originating from the Declaration of Helsinki and good clinical practices.

5.3 Safety

MammoMARK® Biopsy Site Identifier(s) and CorMARK® Biopsy Site Identifier devices are intended to be used for follow-on tracking of breast biopsy sites where the imaged evidence may be removed by the biopsy. The devices are designed for use in both open and through the skin [percutaneous] breast biopsy procedures.
The target population is adult patients presenting with breast abnormalities that require diagnostic sampling.

Based on the clinical evidence analyzed, the safety of the MammoMARK® Biopsy Site Identifier(s) and CorMARK® Biopsy Site Identifier devices when used as intended, provides evidence that the MammoMARK® Biopsy Site Identifier(s) and CorMARK® Biopsy Site Identifier devices are state of the art and conforms to the requirement for safety.

6.0 Possible Diagnostic or Therapeutic Alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

6.1 General Description of Therapeutic alternatives

- No-marker used: Usually done if in an advanced stage of cancer and treatment option is a complete mastectomy or the choice of having an open surgical biopsy.
- Bare Metallic Marker: The device has no material encapsulated around the metal marker.
- Metallic Marker with absorbable material: The device will have absorbable material encapsulated around the metal marker.

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7.0 SUGGESTED TRAINING FOR USERS

This device should be used only by physicians trained in percutaneous breast biopsy procedures.