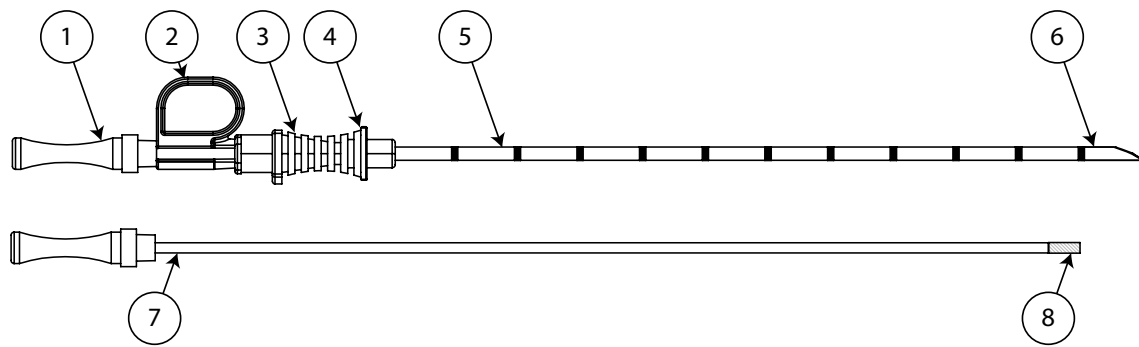


Sirius Pintuition Seed 14G

Instructions for Use.



1. Green pusher handle
2. Translucent removable spacer
3. Translucent hub
4. Black Line (Needle Top)
5. Sharp outer needle
6. Ultrasound enhanced tip
7. Blunt inner pusher
8. Pintuition Seed

Name of the Medical Device

Sirius Pintuition Seed 14G x 12cm (SPS12)
Sirius Pintuition Seed 14G x 20cm (SPS20)

Description

The Sirius Pintuition Seed (Pintuition Seed) is part of the Sirius Pintuition Localization System (Pintuition Localization System).

The Pintuition Seed is a single-use, sterile medical device, consisting of an implantable magnetic seed which is supplied preloaded within a delivery needle.

The Pintuition Seed is intended to be placed percutaneously in the breast to mark a lumpectomy site intended for surgical removal.

The Pintuition Seed is preloaded within the needle.

The sharp outer needle is fitted with a translucent hub on the distal end. The hub has a black line on the top side to identify the orientation of the needle bevel.

The exterior of the outer needle has centimeter depth markings engraved. The tip of the outer needle has an ultrasound-enhanced finish. The needle is covered using a protective sleeve (not shown in the figure above).

The blunt inner pusher is fitted with a green pusher handle.

The device contains a removable translucent spacer that clamps onto the inner pusher and in the translucent hub of the outer needle to prevent unwanted seed deployment during transport and positioning of the needle.

Possible Complications and Adverse Events

During routine use, complications may occur at any moment during or after the localization procedure.


Possible complications of implantation of the Pintuition Seed include, but are not limited to: hematoma, seroma, bleeding, infection, damaging of neighboring tissues, allergic reaction and pain.

MR Safety Information

MR CONDITIONAL - Non-clinical testing has demonstrated the Pintuition Seed is MR Conditional. A patient with the Pintuition Seed can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5T and 3.0T
- Maximum spatial field gradient of 3,000G/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2W/kg (First Level Controlled Operating Mode)

Under the scan conditions defined above, the Pintuition Seed is expected to produce a maximum temperature rise of less than 2 °C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the Pintuition Seed extends approximately 60 mm from the Seed when imaged with a gradient echo pulse sequence and a 3.0 T MRI system. Use of Pintuition Seed under the scan conditions defined above may induce pain and/or rotation at the implant site.

 **WARNING.** The delivery needle is **MR UNSAFE**. Do not attempt to implant the Pintuition Seed using MRI guidance.

Intended Purpose

Indication for Use

The Pintuition Localization System is intended as a magnetic soft tissue localization system.

The Sirius Pintuition Seed is intended to be placed percutaneously in the breast to mark temporarily (<30 days) a lumpectomy site intended for surgical removal. Using imaging guidance (such as ultrasound or radiography) or aided by non-imaging guidance (Sirius Pintuition Detector) the Sirius Pintuition Seed is located and surgically removed with the target tissue.


The Sirius Pintuition Detector is intended for the non-imaging detection and localization of the Sirius Pintuition Seed that has been implanted in a lumpectomy site intended for surgical removal.

Patient Target Groups

The Pintuition Seed is not intended for a specific patient group. It may be used for any patient age 12 or over for which surgical removal of a tissue of interest within soft tissue is medically indicated. There are no further restrictions on patients' gender, weight, health or condition.

Intended Users

The Pintuition Seed and Needle are intended to be used by a Medical Doctor and may be prepared, retrieved and/or opened by a Medical Nurse or someone with comparable credentials (medically trained users).


 **CAUTION:** This device is only intended to be used by competent and qualified medical doctors and teams in medical environments.


Contra-Indications


- **WARNING.** Do not use the Pintuition Seed in other tissues than named under "Indication for Use", for example do not use in organs, liver, central nervous system, vascular system, heart, lung, eyes or brain. Please note that this list is **not** exhaustive.
- **WARNING.** Do not use the Pintuition Seed in tissue that is clinically proven to be infected.
- **WARNING.** Keep at least 5 cm distance between the Pintuition Seed and any implanted active device such as a pacemaker, cardioverter defibrillator or other electrically powered implant.


Procedures


Implantation

 **WARNING.** The delivery needle is SHARP. Please handle and dispose with care according to biohazard procedures.

 **CAUTION** is advised when using this device with patients that have a breast prosthesis to prevent puncturing of the prosthesis.


 **CAUTION** is advised when using the device near the thoracic wall. Place the needle parallel to the thoracic wall to prevent accidental thoracic wall puncture.

 **CAUTION.** The device is intended only for use in soft tissues. If during preloaded needle advancement a resistance is encountered, carefully correct the direction of the needle to avoid the obstacle. Never use excessive force.

 **CAUTION.** Pintuition Seeds placed in close proximity (<50mm) may impair detection range or accuracy. If multiple seeds are required, space them sufficiently apart and/or proceed with care.

1. Check packaging and product for damage and use-by date.
2. Visualize the tissue of interest using a suitable imaging modality (ultrasound or x-ray) before attempting to implant the Pintuition Seed.
3. Locally anesthetize the tissue if required or indicated as per local procedures.


> Continue reading on the other side


 **CAUTION:** The Pintuition Seed is not intended to be used as a permanent tissue marker. The consequences of implantation longer than 30 days are unknown.


The Pintuition Seed and delivery needle are visible on ultrasound imaging and x-ray imaging.


When used together with the intra-operative Sirius Pintuition Detector (Pintuition Detector), the Pintuition Seed is intended to be used to guide the surgeon in excising the tissue of interest.


The Pintuition Detector is the only detection system qualified to detect the Pintuition Seed.

 **CAUTION:** Use the Pintuition Seed only after you have completely read and understood these instructions for use.

 **CAUTION:** Handle in an appropriate manner to prevent contamination

 **WARNING.** The device is SINGLE USE ONLY – DO NOT REUSE. Reuse of this device bears the risk of cross-contamination between patients.

 **WARNING.** This device is supplied STERILE. Do not attempt to resterilize as the sterility of the device cannot be guaranteed. Every type of resterilization increases the risk of device faults and unwanted effects because of material degradation.

 **NOTE.** This Instruction for Use leaflet covers the Pintuition Seed and its delivery needle. The Pintuition Detector is supplied with a separate instruction for use document.



Pintuition Seed (Implantable)

The Pintuition Seed is a single-use, sterile implantable seed that is 5 mm long and 1.6 mm in diameter. The exterior is composed of biocompatible Titanium.

The Pintuition Seed is magnetic, and designed to be detected using the Pintuition Detector. The Pintuition Detector is able to detect the seed up to 5cm from the probe tip.

The Pintuition Seed is visible on ultrasound and x-ray imaging.

The Pintuition Seed is intended to be implanted using the preloaded delivery needle.


Delivery needle

The delivery needle is a preloaded, sterile, 14-gauge hypodermic needle. It consists of a sharp outer needle and a blunt inner pusher.


Sirius Pintuition Seed 14G

Instructions for Use.

4. Make a small incision in the skin to facilitate skin puncture if required or indicated as per local procedures.
5. Open the packaging in an aseptic manner.
6. Remove the product from packaging and transfer to the (sterile) work area in an aseptic manner.
7. Safely and gently remove the protective sleeve from the needle.


 **CAUTION:** After removal of the protective sleeve, keep the needle upright or at least horizontal during handling to prevent unwanted seed loss.

8. Slowly advance the needle percutaneously until the needle tip is clearly visible inside the tissue of interest using a suitable imaging modality (ultrasound or x-ray).
9. Confirm the correct location of the needle tip in the tissue of interest using a suitable imaging modality (ultrasound or x-ray). Reposition the needle if required and confirm again.

 **CAUTION.** The depth markings on the needle are for general reference only.




















10. Remove the spacer by gently pulling it slightly away from the needle.
11. Gently push the green handle of the inner pusher to deploy the Pintuition Seed into the tissue of interest.
12. In a swift and continuous movement, retract the needle whilst rotating.
13. It is advised to confirm correct deployment of the Pintuition Seed using a suitable imaging modality (ultrasound or x-ray) or the Pintuition Detector.
14. Dispose of the needle using the procedures for safe disposal of needles and syringes in your institute.

Removal

 **CAUTION.** Use the Pintuition Detector only after you have completely read and understood its instructions for use.

1. Determine the location of the Pintuition Seed using the Pintuition Detector or a suitable imaging modality (ultrasound or x-ray)
2. Excise the tissue of interest using the Pintuition Detector or a suitable imaging modality (ultrasound or x-ray)
3. Confirm using the Pintuition Detector or a suitable imaging modality (ultrasound or x-ray) that the Pintuition Seed is present in the specimen.

Symbols on the label and in this document

Symbol	Description
	Medical Device
	Catalog number
	Quantity
	Batch Code
	Do not re-use
	Do not re-sterilize
	Use-by date: YYYY-MM-DD
	Sterilized using Ethylene Oxide
	CE-Mark as specified in European Guideline 93/42/EEC regarding medical devices
	Consult instructions for use
	Warning
	Caution
	MRI Conditional Safe
	Manufacturer
	Manufacture date: YYYY-MM-DD
	Keep away from direct sunlight
	Keep dry
	Do not use if package is damaged
	For Prescription Use Only.

Name and address of manufacturer



Made in the Netherlands

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The information contained in this Instructions for Use may be updated without prior notice. Please refer to www.sirius-medical.com/support or use the QR code on page 1 for the latest version.

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