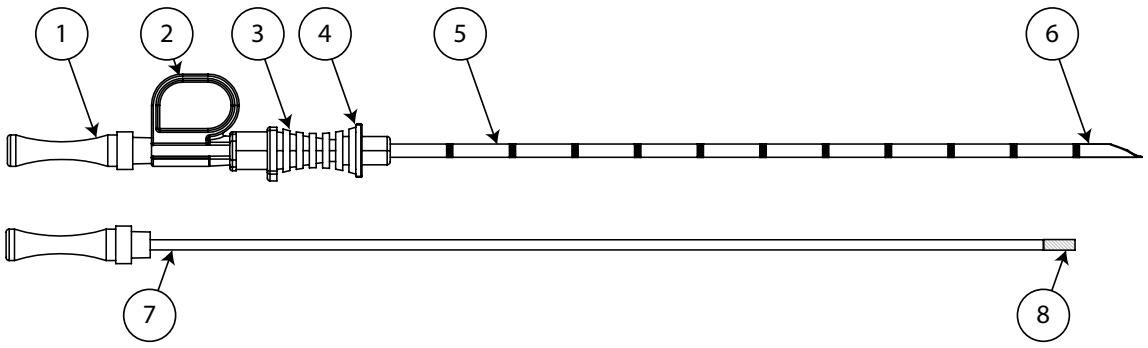
Sirius Pintuition Seed 14G

Instructions for Use.

sirius medical



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 implanted into a tissue of interest within soft tissue. The tissue of interest should be planned for surgical removal within 180 days after implantation.

CAUTION: The Pintuition Seed is not intended to be used as a permanent tissue marker. The consequences of implantation longer than 180 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.

Scan for Sirius support webpage

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.

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.

Intended Purpose

Indication for Use

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

The magnetic Pintuition Seed is indicated for pre-operative percutaneous implantation into soft tissue (glandular, fibrous or fatty tissue of breast; lymph nodes in the axillary and inguinal region; subcutaneous tissue and skeletal muscle tissue) for temporary marking (<180 days) of a tissue of interest (e.g. tumor or a suspected lesion) indicated for surgical removal.

Using the Pintuition Detector as magnetic guidance or, alternatively, image guidance (ultrasound or x-ray), the Pintuition Seed can be intra-operatively localized and removed together with the tissue of interest.

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.

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 this device can be safely scanned in an MR system meeting the following conditions:

- Maximum static magnetic field of 3 Tesla
- Maximum spatial field gradient of 900G/cm (9 T/m)
- Maximum force product of 16,000,000 G^2/cm (16 T^2/m)

In non-clinical testing, the image artifact caused by the device extends approximately 59.9 mm from the Pintuitition Seed when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

WARNING. The delivery needle is **NOT SAFE** for use during MRI. Do not attempt to implant the Pintuition Seed using MRI guidance.

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.
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 the 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
MD	**M**edical **D**evice
REF	Catalog number
QTY	Quantity
LOT	Batch Code
	Do not re-use
STERILIZE	Do not resterilize
	Use-by date: YYYY-MM-DD
STERILE EO	Sterilized using Ethylene Oxide
CE	CE-Mark as specified in European Guideline 93/42/EEC regarding medical devices
	Consult instructions for use
	Warning
	Caution
MR	MRI Conditional Safe
	Manufacturer
	Manufacture date: YYYY-MM-DD
	Keep away from direct sunlight
	Keep dry
	Do not use if package is damaged
Rx	For prescription use only[1]

[1] Only in FDA regulated territories.

Name and address of manufacturer

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CE 0344

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