SchurSign® Tissue Marker Instructions for Use

Caution Rx Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

PRODUCT DESCRIPTION

SchurSign Tissue Marker consists of a radiographic soft tissue marker and a delivery system. SchurSign is a sterile, single patient use, discrete marker that is visible on standard radiographs (x-ray, mammography) as well as ultrasound, and Magnetic Resonance Imaging (MRI).

SchurSign Tissue Marker is placed into soft tissue during open, percutaneous, or endoscopic procedures to mark a surgical location.

SchurSign Tissue Marker is comprised of chitosan filled with Barium Sulfate. SchurSign Tissue Marker delivery system is a distal delivery needle tip, rigid shaft, sterile, and single patient use preloaded delivery system incorporating the SchurSign Tissue Marker.
The delivery system consists of a cannula with a handle, a push rod with a plunger, and an end cap. The tissue marker is retained within the delivery system until placement is desired, where it is delivered through the end port by fully depressing the plunger into the handle. The SchurSign Tissue Marker delivery system is used to place the SchurSign Tissue Marker into soft tissue during open, percutaneous, or endoscopic procedures to radiographically mark a surgical location. The delivery system device has a bevelled 12 cm / 14 to 10 gauge needle with 1 cm depth marks and a plunger.

SchurSign is available in seven different sizes:

Model	Diameter (mm)	Length (mm)
SchurSign 1.5-5	1.5	5
SchurSign 1.5-8	1.5	8
SchurSign 2.0-5	2.0	5
SchurSign 2.0-8	2.0	8
SchurSign 2.0-10	2.0	10
SchurSign 2.5-10	2.5	10
SchurSign 3.0-10	3.0	10

Note: Up to three implants with a length of 5 mm and diameter of 1.5 mm maybe used at a time while only one implant with a length of >5 mm and diameter of >1.5 mm maybe used at a time.

INDICATION

Under supervision of a healthcare professional (Rx)

- SchurSign Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

CONTRAINDICATIONS

This device is not intended for use except as indicated.

⚠ WARNINGS

- Do not insert SchurSign Tissue Marker into blood vessels.

PRECAUTIONS/PRECAUTIONARY MEASURES

- Only physicians qualified in the appropriate surgical techniques and procedures should use this device.
- Only physicians having adequate training and familiarity with minimally invasive biopsy procedures. Consult medical literature relative to techniques, complications, and hazards prior to performing any minimally invasive procedure.
- Minimally invasive instruments may vary in size from manufacturer to manufacturer. When minimally invasive instruments and acces sories from different manufacturers are employed together and in conjunction with the SchurSign Tissue Marker in a procedure, verify compatibility prior to initiation of the procedure.
- SchurSign Tissue Marker is not recommended for use in patients with breast implants.
- Do not use in the presence of infection.
- SchurSign Tissue Marker is supplied sterile, in a sealed package, and is intended for single use only. Do not re-sterilize and/or re-use this device, as it may damage the device or injure the patient and/or user. Carefully examine each unit to verify that neither the contents nor the sterile package show any sign of damage. **Do not use if damaged.**
- **Do not re-sterilize.** This may damage or distort contents. Unless the packaging is damaged, SchurSign Tissue Marker will remain sterile until used or expired.
- Prior to use, do not expose package to organic solvents, ionizing radiation or ultraviolet light.
- After use, device may be a potential biohazard. Handle accordingly and dispose of in accordance with accepted medical practice and applicable local, state, and federal regulations.
- The device must be used in an operating room in hospital or equivalent environment.
- Chronic implantation of the subject device in swine up to 84 days results in peri-device granulomatous inflammation surrounded by fibrous encapsulation, with variable capsular/peri-capsular small lymphocyte infiltration.
- Up to three implants with a length of 5 mm and diameter of 1.5 mm maybe used at a time while only one implant with a length of >5 mm and diameter of >1.5 mm maybe used at a time.

POSSIBLE ADVERSE EVENTS

Possible adverse reactions that may be associated with the use of SchurSign Tissue Marker are similar to those associated with the use of other marking devices. These may include: pain, hematoma, hemorrhage, tissue injury, infection and organ puncture, migration, inter-operative loss, misplacement and delivery tip shear. The patient should be counseled to report adverse events. Physicians should report device-related adverse events to SurgMark GmbH via email: info@surgmark.com

INFORMATION TO BE COMMUNICATED TO THE PATIENT

Information concerning the benefit and risks of endoluminal procedures with or without tissue marker placement.

INSTRUCTIONS FOR USE

Verify compatibility of all minimally invasive instruments and accessories prior to use (refer to Precautions).

1. Inspect the SchurSign Tissue Marker package to ensure that the package integrity has not been compromised. The product is sterile through the expiration date unless the seal is broken.
2. Using standard sterile aseptic technique, remove the SchurSign Tissue Marker from the package. Remove the tip cover. Inspect the device for signs of damage.
3. Advance the device to the targeted site. Locate the target area using appropriate imaging technique.
4. Completely advance the push rod forward to release the SchurSign from the device.
5. With the push rod completely advanced, slowly remove the device.
6. Dispose of the device properly.
7. Confirm the final position of SchurSign Tissue Marker with desired imaging.

HOW SUPPLIED

SchurSign Tissue Marker is individually packaged and supplied with ten (10) packages to a box.

STORAGE

There are no special storage instructions for SchurSign Tissue Marker. Prior to use, the product should be at room temperature, 15°C – 30°C (59°F – 86°F).

WARRANTY

The manufacturer warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness.
Handling and storage of this device as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond the manufacturer's control directly affect the device and the results obtained from its use. The manufacturer's obligation under this warranty is limited to the replacement of this device and the manufacturer shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. The manufacturer neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

STERILIZATION

SchurSign has been sterilized by ethylene oxide (EO).

MRI SAFETY INFORMATION

The SchurSign marker is composed of chitosan and barium sulfate. Both materials are electrically nonconductive, nonmetallic, and nonmagnetic. Therefore, SchurSign is considered MR Safe.

INQUIRIES

For further information, orders or to report adverse effects, please contact:
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EXPLANATION OF THE SYMBOLS USED

	Expiration date: Year-Month-Day
15°C 59°F – 30°C 86°F	Temperature limits for storage
LOT	Lot number
REF	Catalog number
STERILE EO	Sterilized by EO
Rx Only	Prescription only
	Quantity in package
	Consults instructions for use
	Do not use if package is damaged
	Do not re-sterilize
	Do not re-use
	Manufacturer
	Keep dry
LATEX	Not made with natural rubber latex

FDA Clearance Number: K230836

Delivery Device is MR Unsafe.
Tissue Marker is MR Safe.

MANUFACTURER

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IFU-01 Rev. 00