

SchurSign[®] is a tissue marker based on the biomaterial chitosan.

It is designed for use in:

- marking of the site of collection of a breast biopsy
- permanent marking of suspicious lesions of the breast

SchurSign[®] is specifically designed to be visible in ultrasound, mammography, CT-scanning and MRI.

For improved imaging in mammography and CT, the marker contains barium sulfate.

When placed into tissue SchurSign[®] absorbs water and increases in size when fully hydrated (Fig. 1).

About Chitosan:

- Chitosan is a highly biocompatible biomaterial derived from chitin
- Chitosan is a polysaccharide and acts as a hydrogel

FDA cleared medical applications for chitosan include:

- Wound dressings and hemostatic agents
- Implants for nerve regeneration

Application and applicator

SchurSign[®] is supplied as a sterile packed and preloaded, single use applicator (Fig. 2).

The marker is placed in the tissue under ultrasound control by insertion of the applicator and triggering of the injection mechanism.

Specification of the applicator

The applicator has a beveled, 12 cm, stainless steel needle with centimeter markings.

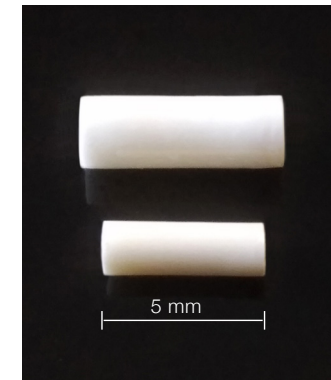


Fig. 1 SchurSign[®] before (bottom) and after (top) hydration



Fig. 2 Applicator for SchurSign[®]

Information for the healthcare professionals

INDICATIONS FOR USE

Under supervision of a healthcare professional (Rx)

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

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

TISSUE MARKER MATERIAL

SchurSign® Tissue Marker is comprised of chitosan and barium sulfate.

DELIVERY SYSTEM

SchurSign® Tissue Marker is delivered with a sterile, single patient use, preloaded applicator holding the SchurSign® Tissue Marker.

The applicator is secured with a protective cap, which must be removed prior to use.



Appearance of SchurSign® in ultrasound



Appearance of SchurSign® in mammography

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 biopsy and/or surgical location. The delivery system device has a beveled 12 cm / 14 to 10 gauge needle with 1 cm depth marks and a plunger.

AVAILABLE SIZES

SchurSign® is available in seven different sizes:

MODEL	Diameter	Length
SchurSign® 1.5-5	1.5 mm	5 mm
SchurSign® 1.5-8	1.5 mm	8 mm
SchurSign® 2.0-5	2.0 mm	5 mm
SchurSign® 2.0-8	2.0 mm	8 mm
SchurSign® 2.0-10	2.0 mm	10 mm
SchurSign® 2.5-10	2.5 mm	10 mm
SchurSign® 3.0-10	3.0 mm	10 mm