

Product Specification Sheet

ORDERING INFORMATION

Product name	BioXmark®
Item number	11110535
Product code	1111
IFU languages	CS-SL-SK-HU
Sales unit	Box w/ 5 x 1 ml
Box size / total weight	76.5 x 17 x 87.5 mm / 25.5 g



PRODUCT INFORMATION

Indications	BioXmark® is indicated for use to radiographically mark soft tissue. BioXmark® is intended to mark tissue for at least 2 months after implantation.
Product description	<ul style="list-style-type: none"> • BioXmark® is a single use, implantable medical device consisting of a sterile transparent liquid in a one-point-cut (OPC) glass ampoule • Each ampoule contains 1 ml liquid (nominal volume) • Sterilized using steam • Magnetic Resonance (MR) safe • Upon injection of the BioXmark® liquid into soft tissue, efflux of ethanol leads to the formation of a radiopaque, sticky and gel-like fiducial marker <i>in-vivo</i>
Product components	The liquid is a mixture of ethanol, sucrose acetate isobutyrate (SAIB) and an iodinated and acylated derivative of sucrose (x-SAIB).
Storage instructions	Store at 2–25 °C. Keep away from sunlight.
Shelf-life	3 years.
Contraindications	Do not use in patients with known hypersensitivity to iodine or any other component in BioXmark®. Do not use in pregnant women and pediatric patients. Use of BioXmark® in these populations has not been investigated and teratogenicity tests have not been performed.
Precautions	BioXmark® must be handled only by qualified healthcare professionals. Injection of BioXmark® requires experience with implantation of fiducial markers or with taking biopsies from the tissue intended for injection of BioXmark®. See Instruction for Use for detailed precautions and warnings.
Appearance	Upon injection of the BioXmark® liquid into soft tissue, efflux of ethanol leads to the formation of a radiopaque, sticky and gel-like fiducial marker <i>in-vivo</i> .
Usage	BioXmark® is used as a fiducial marker and is visible on all relevant imaging modalities including MRI. See user guidance / Instructions for Use .
Compatible equipment	Can be implanted with standard equipment for percutaneous or endoscopic injections.

CONTACT

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