



Instruction for Use

Snap-On Spherz Passive Retro Reflective Marker
Sterile
For Single Use Only

Indication for Use

Intended to be used as image guided surgery system as accessory to aid in auto-registration and localization of rigid patient anatomical structure in either open or percutaneous image guided surgery procedures. It is indicated for any medical condition in which the use of an image guided surgery system may be considered to be appropriate.

Snap-On Spherz Passive Retro Reflective Marker can be used in the following procedures:

- Stereotactic brain surgery
- Endoscopic Sinus Surgery
- Pedicle Screw Placement
- Reconstructive orthopedic surgery
- Soft tissue treatment

Other applications are not considered and are within the responsibility of the user.

Device Description

Sterile reflective markers for use as an accessory to aid in registration and localization of patient anatomical structures in either open or percutaneous image guided surgery. markers are radiopaque and are visible under X-ray and CT modalities.

Precautions

- For single patient use only.
- DO NOT use if package or component is damaged. DO NOT reuse, reprocess, or repackage this device. DO NOT modify any system component or accessory unless otherwise specified.
- Use only IZI-approved system components and accessories, unless otherwise specified.

Snap-On Spherz Passive Retro Reflective Marker Procedure

1. Open bag and drop clamshell pack onto sterile field without contaminating pack.
2. NOW UNDER STERILE CONDITIONS open clamshell pack and extract markers.
3. Place marker on mounting post and press downward. Snap indicates marker is fully seated in socket.
4. To remove marker grasp near base and pull upward.
5. Concurrent use of other manufacturer spheres may adversely affect performance.



STORAGE

Products must be stored in the original unopened packaging in a dry place. Storage temperature range must be considered. Proper care should be taken to ensure that the product will not be damaged or rendered non-sterile.

Limitation of Liability

IN NO EVENT SHALL IZI MEDICAL BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR EXEMPLARY DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE PRODUCT, BASED UPON BREACH OF CONTRACT (INCLUDING BREACH OF WARRANTY).



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