



Instruction for Use

Threaded 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.

Threaded 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. Align marker post hole to marker mounting post on surgical instrument.
4. Press downward until the base of the marker touches the top of the threads on the mounting post.
5. Rotate the marker clockwise to engage the threads.
6. To remove the marker, rotate the marker counter-clockwise until the threads are fully disengaged and then lift upward.
7. 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).



Service Representatives and Requests for Information

For service, technical support, requests for information or reorder information, contact:



IZI Medical Products
5 Easter Court, Suite J
Owings Mills, MD 21117 USA
+1 410 594-9403 (T)
+1 410 594 0540 (F)
www.izimed.com

Product Returns

To return product, contact IZI Medical Inc. at (410) 594-9403