Surgical Precision

www.ilumark.com
“The success of our innovative and premium-quality products is based on our open and intensive contact with our customers, creative space for our employees and fair dealings with our partners. Building and cultivating reliable and long-term relationships is important to us.”

Holger Rossner
Managing director, ILUMARK
ILUMARK GmbH located in Feldkirchen near Munich is an international company which has specialized in developing, producing and distributing single-use products used with computer-assisted navigation systems. Managing director Holger Rossner founded the company in 2008 after having gained more than 15 years of experience in the field of computer-assisted navigation. Mr. Rossner himself is today head of development and constantly strives to find ways of offering user-friendlier product innovations at fair prices. Experienced surgeons and surgical nurses support our development team.

Our continuously growing international clientele includes prestigious hospitals and surgeons from the field of neurosurgery, orthopedics, maxillofacial and ENT surgery.

Our goal is to expand our product range and to develop new sales markets.
We place the highest demands on functionality, quality and customer care

Innovative product developments
Computer-assisted surgeries are complex operations demanding the highest precision and concentration. To support the surgeons during these operations in the best way possible, we work steadily to deliver innovations and improvements to our products, which provide the users with a clear benefit when carrying out image-guided surgeries.

Highest quality standards
Our constantly high level of product quality and 100% reliable sterility are guaranteed by state-of-the-art production processes and test methods. As well as meeting national quality standards, it is also very important to us to fulfill international quality demands. This is why we have acquired all international approvals for our products, incl. 510(k) clearance.

Customer care
The wishes and needs of our clients are important to us. We are happy to help our customers at any time via telephone or meet in person for consultations, individual requests or to discuss suggested improvements.

In the production and distribution of our products, we are also very concerned about the environment. In general, we try to keep transportation routes as short as possible and have our products produced, packaged and sterilized exclusively in Germany.
Solutions for surgical navigation

Sophisticated products and packaging for supreme user comfort

By specializing in products, which are required in the use of imageguided navigation systems, we possess extensive know-how in this field. Our knowledge is reflected in our technically sophisticated products and packaging solutions. In addition to quality and functionality, user comfort is always the primary focus for us.

Our portfolio includes for example navigation markers with a timesaving mounting method to make it easier for the surgical nurses to prepare for a navigated surgical operation. In addition, we offer several packaging sizes for our products so that our customers can order the quantities they need and no longer have to dispose of any unused products.
Ilumark Navigation Marker Accuracy Test

Scope
Verification of optical accuracy of ILUMARK Navigation Markers in comparison with commercially available reflective marker spheres. The products under test as well as the Benchmark Markers are equipped with a snap mechanism for fixation to an instrument post.

Design approach
An independent laboratory² performed the comparison test. All tests have been conducted in a controlled laboratory environment and are reproducible. 3D position measurements of ILUMARK Navigation Markers have been compared to Benchmark Markers utilizing a standard 3D Optical Tracking System, widely used for Image Guided Surgery Systems. The Navigation Marker under test was placed relative to four reference markers on a verification tool. Rotating the test marker independently to different orientations (top view = 0°, +- 40°, +- 70°) allows the simulation of a clinically relevant setup (see Fig. 1). The setup was validated using high accuracy reference markers.

Background Information
ILUMARK started distributing sterile, reflective Navigation Markers, suitable for most Image Guided Surgery (also called Computer Assisted Surgery) systems in early 2010. ILUMARK Navigation Markers are 100% compatible with established fixation pin standards. Two standards are available: Snap fixation mechanism with a sphere diameter of 11.5mm and Screw fixation mechanism with a sphere diameter of 13.0mm. Many IGS companies using Navigation Markers with snap fixation receive those from subcontractors and sell those relabeled under their own brand to their end customers. Based on a patented manufacturing process ILUMARK now offers an attractive alternative regarding price, quality and service. To support prospective buyers in their decision, ILUMARK has commissioned an accuracy comparison study at an accredited laboratory.

Testing procedure
Verification of test procedure Initially the accuracy and applicability of the 3D Optical Tracking System was performed according VDI/VDE 2002 Guideline 2634 Part 1: “Optical 3D-Measurement – Imaging systems with point-by-point probing.” The setup was considered qualified.

Setup of verification tool
Five retro-reflective spheres are placed in a verification tool (Fig. 1). The marker under test is positioned in the center of the verification tool and is moved relative to four reference markers to five different orientations (top view = 0°, +- 40°, +- 70°, Fig. 2a, b, c). The test aims to determine a sphere's three-dimensional deviation from a reference position when the sphere is rotating around its mechanical centre. The low mechanical eccentricity of 20 μm could lead to the ideal case of all rotating positions having nearly identical deviation values. Ideally, this could mean that mechanical and measured sphere centre is always identical. Both outer points are analyzed in reference to a locator. The deviation is the expected reference position of the tested sphere (Fig. 1 centre) to the actual position within the local locator coordinate system. This testing procedure is especially efficient revealing high measurement deviations caused by faulty retro-reflective coating, as the optical image of the sphere does not correspond with its mechanical position. Therefore, the testing tool is an efficient mechanical tool for the optical validation of retro-reflective spheres. Due to practical relevance, two different cameras to verification tool distances were used. Position A describes a distance of 1.5m while position B describes a distance of 2.5m.
**Measurement**
As quality assurance and plausibility test, the first test run was conducted with known reference markers. The system-based noise was hereby determined to be 0.2mm at a distance of 1.5m and 0.4mm at 2.5m. Following this verification test, three Benchmark Marker and three ILUMARK Navigation Markers were tested in five orientations (0°, +40°, +70°, -40°, -70°).

**Results**
Calculating a measurement system caused measuring noise of 0.2mm at a distance of 1.5m, the Benchmark Markers are located (in average - for all five orientations) at 0.49mm and ILUMARK Navigation Markers (in average - for all five orientations) at 0.45mm; approx. 0.2mm to 0.3mm above the theoretically possible value.

Calculating a measurement system caused measuring noise of 0.4m at a distance of 2.5m the Benchmark Markers are located (in average - for all five orientations) at 0.55mm and ILUMARK Navigation Markers (in average - for all five orientations) at 0.49mm; approx. 0.1mm to 0.2mm above the theoretically possible value.

Fundamentally ILUMARK Navigation Markers Spheres are better by a margin in Position A as well as in Position B. The accuracy of both manufacturers is, however, well within the laboratories experience values. Possible faults in the markers’ surface decrease with increasing distance. This is caused by the low resolution of the measurement system.

**ILUMARK “Zero Gap”**
ILUMARK Navigation Markers feature technologically high accuracy and also brilliant optical appearance in sphericity and surface finish. Marker Spheres of many other suppliers show a considerable wide gap (Fig. 4a) at the equator of the sphere. This gap may negatively influence the accuracy of the Navigation Markers. ILUMARK’s new, patented production process allows the manufacturing of Navigation Markers with ZERO GAP (Fig. 4b).

**Conclusion**
ILUMARK Navigation Markers show a slightly better accuracy performance than other currently available Benchmark Marker Spheres with snap fixation. Clinics and hospitals that would like to make use of the cost savings associated with ILUMARK Navigation Markers can assume to receive similar or even slightly better performance regarding navigation accuracy.

Easy withdrawal of blisters through a convenient dispenser box, while maintaining an overview of the remaining packages. Double-sterile high-grade blisters with high quality Tyvec foil.

- Compatible with BrainLAB Navigation systems
- Sterilized by EtO

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<th>Article</th>
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| ILUMARK Navigation Markers - Twist (Set 160) | • Bulk pack  
• High volume packaging unit | 2020-160 |
| ILUMARK Navigation Markers - Twist (Set 120) | • Universal packaging unit | 2020-120 |
| ILUMARK Navigation Markers - Twist (Set 40) | • Packaging unit for single marker removal | 2020-40 |

\[1\] registered trademarks of BrainLAB AG
ILUMARK Navigation Markers – Snap
(compatible with Medtronic®(2) and Aesculap®(3) Navigation systems)

Product Information

Navigation Markers - Snap with clip fixation are fully compatible with Medtronic® Stealthstation(2) and Aesculap® Orthopilot(3).

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(2) registered trademark of Medtronic Inc.
(3) registered trademark of Aesculap AG
To whom it may concern,

There may be uncertainty regarding information mentioned or even given about the compatibility of third-party navigation markers supplied by ILUMARK and others. This is a short fact sheet stating simply the TRUE facts.

FACT: All Navigation markers distributed in Australia are made by third party manufacturers!

**ILUMARK and ILUMARK Products**
- ILUMARK has been producing navigation markers since 2009.
- ILUMARK has a worldwide distribution network and more than 200 customers.
- ILUMARK is an ISO 13485 certified company.
- ILUMARK has invested in fully automated manufacturing lines to guarantee the highest quality.
- ILUMARK navigation markers are the only navigation markers that are "MADE IN GERMANY".
- ILUMARK navigation markers are TGA listed (TGA No. 180216 Class Is) and received 510(k) approval in the USA.
- ILUMARK navigation markers are 100% compatible with IGS (Image Guided Surgery) systems from Brainlab and Medtronic. Accuracy tests have been successfully performed using NDI cameras by an independent laboratory. Hence producing a white paper for necessary approval processes, CE, FDA and TGA.
- ILUMARK navigation markers are the only markers with "Zero-Gap" technology.

**IGS Companies**
- There are 2 major IGS companies acting in Australia: Brainlab and Medtronic.
- Brainlab sold their marker business to Northern Digital Inc. (Canada) in 2010 and is no longer manufacturing or distributing navigation markers.
- Medtronic used to source their navigation markers from a third party manufacturer "IZI" and rebranded them as Medtronic markers for customers. They NOW have changed this to NDI from Jan 2012 onwards.
- Brainlab and Medtronic both source their markers from third party suppliers.
- NDI and ILUMARK navigation markers are distributed in Australia through external distributors.
- All navigation markers from ILUMARK, NDI and IZI work. It really comes down to price, quality and service.
- Neither Brainlab nor Medtronic systems would track non-compatible markers, they simply would not work nor track any instruments. There is an option the user can test on screen on their systems to prove this.
- All markers from all third party manufacturers are CE, FDA and TGA APPROVED for use on either Brainlab or Medtronic systems.
- NO company can LEGALLY claim any inaccuracies, reliability, warranty or service issues or questions in any way, shape or form relating to the choice of using ILUMARK on either Brainlab or Medtronic systems! There are now several customers in Australia whom are using ILUMARK spheres with NO affect on their systems service contracts, warranty or reliability. This is a proven fact.
- NDI or Brainlab Markers in Australia are now distributed by a NON BRAINLAB distributor. They NO LONGER represent BRAINLAB, making them third party distributors as PBM.

**Point Blank Medical Facts, PBM**
- We have more than 15 years experience in Image Guided Surgery, especially Brainlab as PBM are EX Brainlab managers that started Brainlab in Australia. We stand by our reputation, credibility and knowledge of navigation systems.
- PBM supply only 100% compatible navigation markers which are CE, FDA and TGA approved.
- PBM and ILUMARK already have a long list of established and satisfied Australian and worldwide customer base using ILUMARK navigation markers, with either their Brainlab and/or Medtronic systems.

We know we supply an equal or better approved product, 100% compatible, and at a better price.
We know you have choices and hope that we have proven that you have another safe and reliable choice, ILUMARK!

Your free choice as a customer should be based on …

Price, Preference, Quality and Service! And the true facts!
Who Are We?

Point Blank Medical is a young Australian-owned medical company headquartered in Sydney with a national footprint across Australia. Point Blank Medical has its roots from 25 combined years of national and international clinical/surgical sales and marketing.

We love spending time in neurosurgical, spinal and orthopaedic operating rooms supporting our products with surgeons and nurses where we can contribute to better patient outcomes.

We have selectively aligned ourselves with “best of breed” suppliers and manufacturers in these specialty areas especially in bone biologics in Neurosurgery and Orthopaedic surgery.

Point Blank Medical is a growing company in targeted niche segments essentially to “stick to our knitting” and to ensure our focus remains on the most important people in our market – patients, nurses and surgeons.

Explore our brochure and we’re sure you will find it enlightening. We hope you will be a frequent visitor and we might have the pleasure to meet you in person.
Any Queries?

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