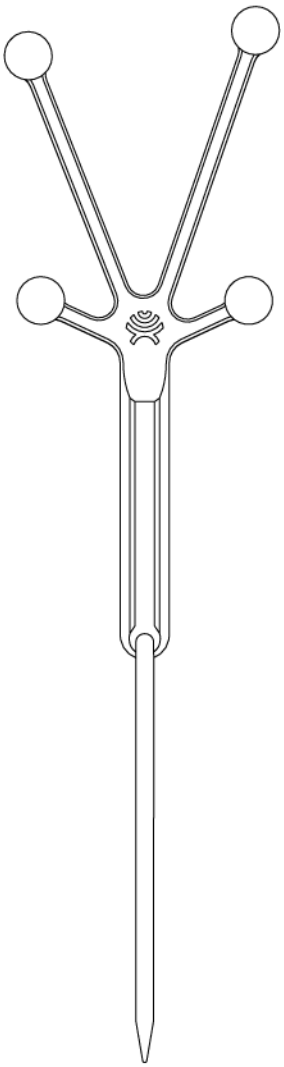
BrightMatter™ Pointer

User Manual

MAN-0640 Revision C



Synaptive

User Manual

Synaptive™ BrightMatter™ Pointer

SYN-0642

Synaptive

MAN-0640 – Revision C issued on June 10, 2021.

These instructions for use are also available in electronic form at www.synaptivemedical.com/eIFU. The electronic instructions for use may be viewed on any device that can access the internet and display PDF files. Access to the electronic instructions for use requires a password; to obtain the password, contact Synaptive Customer Service.

BrightMatter Pointer fulfills all the relevant provisions in Regulation (EU) 2017/745 of the European Parliament and of the Council. Based on this regulation, the CE mark is hereby affixed:

CE 2797

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South Australia, 5000

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EC REP EU Authorized Representative:
Medical Device Safety Service (MDSS)
Schiffgraben 41
30175 Hannover, Germany

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1.0 Product and Safety Symbols

Table 1 ISO 7000 - Graphical symbols for use on equipment - Registered symbols and ISO 15223-1 - Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

Symbol	Title	Reference	Description
	Caution	ISO 7000-0434A	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Manufacturer	ISO 7000-3082	To identify the manufacturer of a product.
	Date of manufacture	ISO 7000-2497	To indicate the date on which a product was manufactured.
	Operator's manual	ISO 7000-1641	To identify the location where the operator's manual is stored or to identify information that relates to the operating instructions. To indicate that the operating instructions should be considered when operating the device or control close to where the symbol is placed.
	Catalog number	ISO 7000-2493	To identify the manufacturer's catalog number, for example on a medical device or the corresponding packaging.
	Serial number	ISO 7000-2498	To identify the manufacturer's serial number, for example on a medical device or its packaging.
	Batch code	ISO 7000-2492	To identify the manufacturer's batch or lot code, for example on a medical device or the corresponding packaging.
	Sterilized using ethylene oxide	ISO 7000-2501	To indicate that the device is provided sterile and has been sterilized using ethylene oxide.
	Do not use if package is damaged	ISO 7000-2606	To indicate that the device must not be used if the package holding the device is damaged, for example on packaging of medical devices.

Table 1 ISO 7000 - Graphical symbols for use on equipment - Registered symbols and ISO 15223-1 - Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied (continued)

Symbol	Title	Reference	Description
	Use by date	ISO 7000-2607	To indicate that the device should not be used after the date accompanying the symbol, for example on a medical device or its packaging.
	Non-sterile	ISO 7000-2609	To indicate that a device that the manufacturer intends to be sterilized has not yet been through the sterilization process.

Table 2 ISO 7010 - Graphical symbols - Safety colors and safety signs - Registered safety signs

Symbol	Title	Reference	Description
	General warning sign	ISO 7010-W001	To signify a general warning.

Table 3 Product Safety Certification Marks

Symbol	Title	Reference	Description
CE	CE mark	N/A	Conformity with the essential requirements set out in the European Directives.
EC REP	European Community Representative	N/A	Appears next to the European Community representative's name and address.

Table 4 Other Symbols

Symbol	Description
Rx only	U.S. Federal law restricts this device to sale by or on the order of a licensed healthcare provider.
MD	Medical Device

2.0 Intended Use with Modus V

BrightMatter Pointer with Modus V is intended to be used as a pointing tool to enable spatial localization and identification by the former system. Since no clinical image can be utilized by the Modus V system, BrightMatter Pointer is not indicated for stereotactic navigation when used with Modus V.

Typical users of the device are medical professionals such as surgeons and other Operating Room staff.

2.1 Intended Use Environment

BrightMatter Pointer and the calibration block are intended for use in hospitals, clinics, and other medical institutions.

3.0 Clinical Benefits

When used with Modus V, Synaptive Pointer provides automatic control of the Modus V camera position and focus, eliminating the need for manual microscope adjustments.

4.0 Warnings and Precautions

WARNING: Risk of Infection

BrightMatter Pointer is not sterile when delivered. The use of non-sterile instruments poses a risk of infection to patients, users, and third parties. Clean and sterilize BrightMatter Pointer before initial use, and before and after every subsequent use, using the cleaning and sterilization instructions accompanying the device.

The materials used in BrightMatter Pointer have been tested and certified for up to 24 hours of exposure to the patient.

WARNING: Risk of Patient Death, Permanent Disability, or Injury Due to Inappropriate Tool Use

Use caution when applying the point of BrightMatter Pointer to any tissue. Do not apply pressure sufficient to damage the tissue.

Use caution when handling BrightMatter Pointer over the patient. Dropping BrightMatter Pointer may injure the patient.

BrightMatter Pointer has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifacts in the MR environment. The safety of BrightMatter Pointer in the MR environment is unknown.

Collisions between BrightMatter Pointer and other surgical tools or devices may create metal debris, potentially harming the patient.

Always inspect BrightMatter Pointer for damage prior to surgery. Never use a tool that appears corroded, damaged, bent, or otherwise distorted from its intended shape. If BrightMatter Pointer does not meet the inspection criteria, the parent system may not function as intended.

Always ensure the tracking spheres are firmly attached to the posts before each use. Loose spheres may detach and fall onto the patient.

Do not attach or remove the reflective tracking spheres over the surgical site. Always attach tracking spheres firmly to ensure that they do not fall and injure the patient.

WARNING: Risk of Procedure Delay Due to Loss of Tool Function

Always ensure the tracking spheres are firmly attached to the posts before each use. If tracking spheres are not firmly attached, the tracking camera may not be able to track the tool.

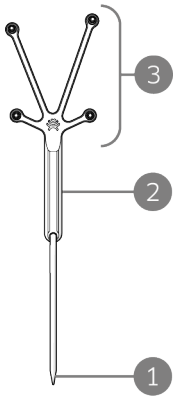
4.1 Incident Reporting

Immediately report any serious incident that has occurred in relation to the use of this device to Synaptive Medical and, for EU customers, the competent authority of your Member State.

5.0 Features and Assembly

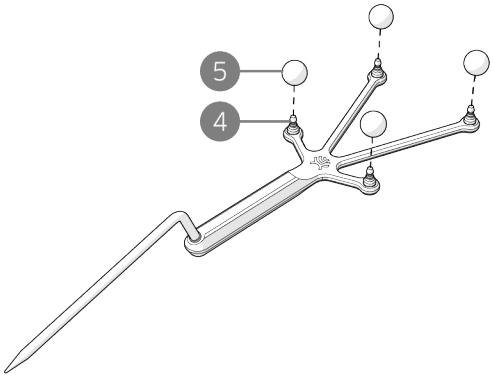
WARNING: Risk of Patient Death, Permanent Disability, or Injury Due to Inappropriate Tool Use

Do not attach or remove the reflective tracking spheres over the surgical site. Always attach tracking spheres firmly to ensure that they do not fall and injure the patient.



1 Tip
2 Handle
3 Tracking array
4 Tracking sphere post
5 Tracking sphere

BrightMatter Pointer features



BrightMatter Pointer assembly

To assemble BrightMatter Pointer, attach a tracking sphere to each post.

6.0 Inspection

Inspect BrightMatter Pointer before each use. If BrightMatter Pointer does not meet the criteria listed below, do not use it. Contact Synaptive customer service for assistance.

- Must be free of corrosion
- Must be free of nicks, dents, or cracks
- The tip must not be bent or otherwise distorted from its original shape

- The tracking array must not be bent or otherwise distorted from its original shape, and the posts for attaching the tracking spheres must be undamaged and perpendicular to the tool

7.0 Calibration and Verification

The calibration and verification process ensures that BrightMatter Pointer is not deformed or damaged.

Use the Synaptive calibration block to calibrate and verify BrightMatter Pointer.

To calibrate BrightMatter Pointer:

1. Insert BrightMatter Pointer through the hole at the top of the calibration block and into the divot in the base.
2. Orient the tool and calibration block so that all eight tracking spheres are visible to the tracking camera.

   The Synaptive software application displays the progress of the calibration.

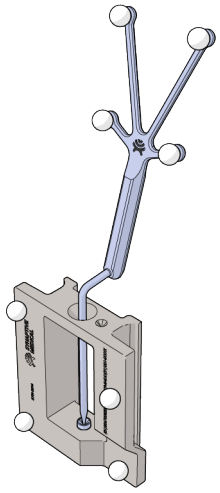


Figure 1 Calibrating BrightMatter Pointer

To verify BrightMatter Pointer:

1. Place the tip of BrightMatter Pointer in the divot on the top of the calibration block.
2. Orient the tool and calibration block so that all eight tracking spheres are visible to the tracking camera.

   The Synaptive software application displays the progress of the verification. When the verification is complete, BrightMatter Pointer is ready for use.

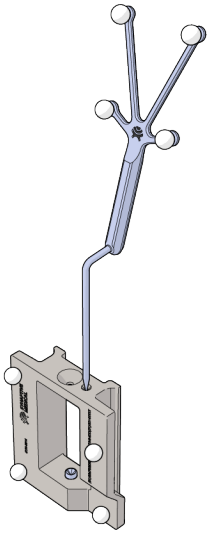


Figure 2 Verifying BrightMatter Pointer

8.0 Using BrightMatter Pointer with a Synaptive Tracking System

To use BrightMatter Pointer with a Synaptive tracking system, hold it so that all the tracking spheres are visible to the tracking camera.

NOTE: For more information about using BrightMatter Pointer with Modus V, see the user manual accompanying Modus V.

9.0 Working with Reflective Tracking Spheres

Synaptive trackable tools are tracked using spherical passive reflective markers. In order to track a tool, all the spheres on the tool must be:

- Properly attached

  To attach the tracking spheres to a tool, push them firmly onto the posts on the tool until they stop. You should feel the spheres snap into place. If a sphere is loose, or is not pushed as far as it will go onto the post, the tracking camera may not be able to track the tool.
- Visible to the tracking camera

  To prevent the loss of tool tracking, avoid obstructing the tracking camera's view of the spheres when using a trackable tool.
- Clean

  If the tracking spheres become soiled during use they can be replaced, but be aware of the following points:
  - Do not attempt to replace tracking spheres over the surgical site
  - If you replace a tracking sphere on a calibrated tool, you must re-calibrate the tool before using it again

Perform a visual inspection before using tracking spheres. Do not use the spheres if they, or their packaging, appear damaged.

The tracking spheres are single-use only and must be properly disposed of after each use.

10.0 Sterilization

The BrightMatter Pointer must be sterilized in an autoclave. For cleaning and sterilization instructions, see the Pointer Cleaning and Sterilization Instructions (Synaptive part number MAN-0544).

The tracking spheres are single-use only and must be properly disposed of after each procedure. **Do not attempt to sterilize the tracking spheres in an autoclave.** Doing so will destroy the tracking spheres and may damage other tools in the autoclave tray.

NOTE: Immediately following a procedure, rinse the sterilizable components as needed to remove visible contaminants and debris. Do not let contaminants dry before cleaning.

11.0 Consumables

The following parts are consumable/disposable products available from Synaptive Medical. To order parts contact salesorders@synaptivemedical.com.

Table 5 Consumables

Part	Part Number	Recommended Minimum Available on Hand
Tracking spheres	SYN-0533	1 box of 48 (12 trays of 4 in box)

12.0 Device Lifetime

BrightMatter Pointer and the calibration block have an expected lifespan of seven years.

13.0 Disposal

Dispose of tracking spheres as pathological waste.

Before disposing of any Synaptive product, contact Synaptive customer service or your supplier for further information.

14.0 Synaptive Customer Service Information

For 24-hour access to clinical and technical support, contact Synaptive customer service.

Phone: 1-844-462-7246 (North America)
1-647-925-3435 (International)
Email: service@synaptivemedical.com

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