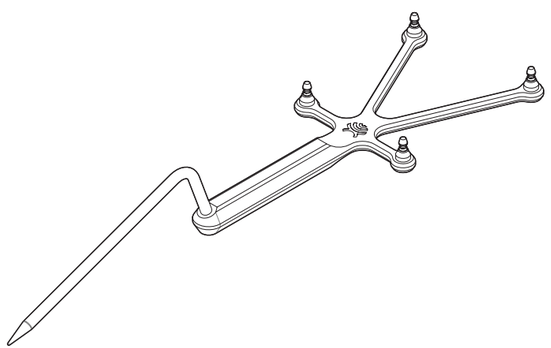
BrightMatter™ Pointer

SYN-0642



Instructions for Use

Indications for Use with BrightMatter Guide

When used with BrightMatter Guide, BrightMatter Pointer is intended to be used for anatomy palpation and as a pointing tool to enable spatial localization and identification by BrightMatter Guide stereotactic navigational systems.

The system hardware and software should be used only by qualified medical professionals who are trained in performing surgery and are familiar with image-guided surgical systems.

Indications for 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.

Product Symbols

Table 1 ISO 7000 - Graphical symbols for use on equipment - Registered symbols

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.
REF	Catalog number	ISO 7000-2493	To identify the manufacturer's catalog number, for example on a medical device or the corresponding packaging.
SN	Serial number	ISO 7000-2498	To identify the manufacturer's serial number, for example on a medical device or its packaging.
	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.
	Fragile, handle with care	ISO 7000-0621	To indicate that the contents of the transport package are fragile and the package shall be handled with care.
	Keep away from rain	ISO 7000-0626	To indicate that the transport package shall be kept away from rain and in dry conditions.
	Humidity limitation	ISO 7000-2620	To indicate the acceptable upper and lower limits of relative humidity for transport and storage.
	Temperature limitation	ISO 7000-0632	To indicate the maximum and minimum temperature limits at which the item shall be stored, transported, or used.
NON STERILE	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.

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.

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

Symbol	Title	Reference	Description
	Refer to instruction manual/booklet	ISO 7010-M002	To signify that the instruction manual/booklet must be read.

Warnings

⚠ CAUTION

Federal law (U.S.A.) restricts this device to sale by or on the order of a surgeon.

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

- The 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 the Pointer in the MR environment is unknown.
- Use caution when applying the point of the Pointer to any tissue. Do not apply pressure sufficient to damage the tissue. Dropping the tool during surgery may injure the patient.
- Impacts between the Pointer and other surgical tools or devices may create metal debris, potentially harming the patient.
- Always inspect the Pointer for damage prior to surgery. Never use a tool that appears corroded, damaged, bent, or otherwise distorted from its intended shape.
- Always ensure the tracking spheres are firmly attached to the tool posts before each use. Loose spheres may detach and fall onto the patient.

⚠ WARNING: Risk of infection

- The 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 the Pointer before initial use, and before and after every subsequent use, using the cleaning and sterilization procedures described in this manual.
- The materials used in the Pointer have been tested and certified for up to 24 hours of exposure to the patient after which the Pointer must be cleaned and sterilized.

⚠ 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.

⚠ CAUTION: Risk of damage to equipment

- Use only the sterilizable storage tray provided by Synaptive Medical to sterilize the Pointer and calibration block. Do not use the tray to sterilize any equipment other than the Pointer and calibration block.
- Do not stack anything on top of or underneath the sterilizable storage tray in the autoclave during sterilization.

MAN-0543 - Revision E issued on June 10, 2021

About the BrightMatter Pointer

The BrightMatter Pointer (SYN-0642) is a tracked surgical instrument that uses passive reflective markers to allow Synaptive systems to identify it and track its location in space.

The Pointer is shipped with a calibration block (SYN-0014), and a sterilizable storage tray (SYN-0596) for sterilizing and storing the Pointer and calibration block.

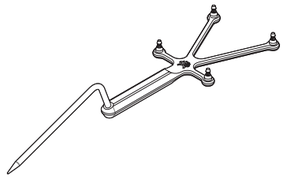


Figure 1 BrightMatter Pointer

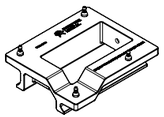


Figure 2 Calibration block

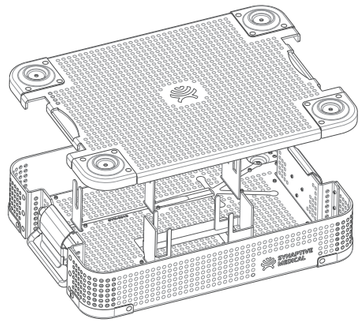


Figure 3 Sterilizable storage tray

Using the BrightMatter Pointer with a Tracking System

NOTE: For more information about using the BrightMatter Pointer with BrightMatter Guide or Modus V, see the user manuals accompanying those products.

To use the Pointer and calibration block with a tracking system, attach a passive reflective marker to each post on the tools and orient the tools so that all the passive reflective markers are visible to the tracking system. During use, avoid obstructing the markers to avoid the loss of tool tracking.

To attach passive reflective markers, push the markers as far down onto the posts as they will go.

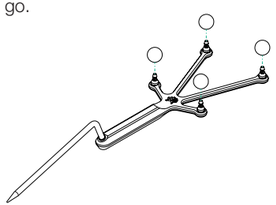


Figure 4 Attaching passive reflective markers to the Pointer

With the spheres attached, follow the instructions in the BrightMatter Guide or Modus V software to calibrate and verify the Pointer using the calibration block.

NOTE: The passive reflective markers are single-use only and must be properly disposed of after each use. If the passive reflective markers become dirty during use and the tool can no longer be tracked, do not attempt to replace them. Clean the markers per the recommended protocol provided by the manufacturer.

To prevent soil from drying on the Pointer, clean it under running water immediately following a procedure.

Inspection

Inspect the Pointer immediately before and after each use. If the Pointer does not meet all the criteria listed below, do not use it. Contact Synaptive Customer Service for support.

- The Pointer must be free of corrosion
- The Pointer must be free of nicks, dents or cracks
- Posts for attaching the passive reflective markers must be undamaged and perpendicular to the tool
- The Pointer must not be bent or otherwise distorted from its original shape

Cleaning and Sterilization

NOTE: The use of cleaning, disinfection or sterilization methods or products not described in this manual may damage the Pointer.

The Pointer, calibration block, and sterilizable storage tray must be cleaned prior to sterilization.

1. If the passive reflective markers are still attached to the Pointer or calibration block, remove them and dispose of them properly.
2. Rinse the components under running tap water to remove visual soil.
3. Using a soft-bristled brush (M16), gently brush the entire surface of each component to remove any remaining debris.
4. Rinse the components in lukewarm running water.
5. Place the components in an automatic washer. The components must not contact any other item in the washer.
6. If you are using an enzymatic detergent such as Enzol® or Prolystica™, run the cycle listed in Table 3.

   If you are using an alkaline detergent such as neodisher® MediClean forte with a pH range 10.4-10.8 (2-10 ml/l, determined in deionized water, 20° C), run the cycle listed in Table 4.

   Use detergents at the manufacturer's recommended concentration and following the manufacturer's instructions.
7. When the washer cycle is complete, dry the components with a lint-free cloth.
8. Inspect the components for cleanliness, paying close attention to hard to reach areas.
9. Inspect the components for any signs of damage or any obvious physical defects (nicks, scratches, distortion in shape, etc.). If any component appears damaged do not attempt to use it and contact Synaptive Customer Service for assistance.

Table 3 Recommended Automatic Washer Parameters for Enzymatic Detergents

Phase	Recirculation Time	Water	Temperature
Pre-wash 1	02:00 minutes	Tap water	Cold tap water
Enzyme wash	04:00 minutes	Tap water	Hot tap water
Rinse 1	02:00 minutes	Reverse osmosis or distilled water	109.4° F (43° C)
Drying	06:00 minutes	N/A	210° F (98.8° C)

Table 4 Recommended Automatic Washer Parameters for Alkaline Detergents

Phase	Recirculation Time	Water	Temperature
Pre-wash 1	02:00 minutes	Tap water	Cold tap water
Wash 1	04:00 minutes	Tap water	109.4° F (43° C)
Rinse 1	02:00 minutes	Reverse osmosis or distilled water	109.4° F (43° C)
Drying	06:00 minutes	N/A	210° F (98.8° C)

To sterilize the Pointer and calibration block:

1. Place the Pointer and calibration block in the sterilizable storage tray provided by Synaptive Medical as indicated by the markings in the tray.
2. Double wrap the tray with 1-ply polypropylene wrap (e.g. Kimguard KC600).
3. Sterilize in an autoclave using the parameters described in Table 5.

Table 5 Recommended Autoclave Parameters

Sterilization Type	Prevacuum	
Method	Moist heat sterilization according to EN ISO 17665	
Preconditioning Pulses	4	
Temperature	270° F (132° C)	273.2° F (134° C)
Minimum Exposure Time*	4 minutes	3 minutes
Minimum Dry Time	30 minutes	30 minutes

* It is acceptable to extend the exposure time if necessary to comply with established protocols at your site. However, because prolonged exposure time may affect product life, carefully inspect tools for damage before use. Prolonged exposure times may also affect the minimum dry time. Always verify that the product is free of moisture after sterilization.

The shelf life of sterilized components depends on the sterile barrier employed and the storage and handling conditions. Your site is responsible for defining and enforcing a maximum shelf life for sterilized instruments.

Consumable Parts

To order consumable parts, contact sales@synaptivemedical.com.

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

Synaptive Medical • 555 Richmond Street West, Suite 800, Toronto Ontario CANADA M5V 3B1
T: 1-844-462-7246 (North America) or 1-647-925-3435 (International) • service@synaptivemedical .com
www.synaptivemedical.com