CLEARPOINT®
NEURO

Bone Anchor
Instructions for Use

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I. Intended Use

Bone Anchor

Indications for Use:

The Bone Anchor is intended to be used with commercially available stereotactic systems for intracranial and neurosurgical procedures which require accurate positioning of compatible small surgical instruments or accessories in the cranium, brain, or nervous systems. It is designed to provide short-term fixation and positioning of compatible neurosurgical instruments or accessories under image guidance.

Intended Users:

The Bone Anchor is intended for use by a Neurosurgeon during minimally invasive neurosurgical procedures.

Warning: This device is intended for single use only. Contents of unopened, undamaged package are sterile. Do not re-sterilize.

Warning: The Bone Anchor should not be subjected to forces which may dislodge it from bone.

Contraindications: This device is not intended to create a seal or barrier from potential infection and has not been tested for long-term (>24 hours) use.

II. Device Description

The Bone Anchor is a single-use device for temporary fixation of surgical instruments or accessories during a single surgical procedure. The Bone Anchor is compatible for use with devices with an outer diameter of up to 2.2 mm and is MR Safe. This device is not intended to create a seal or barrier from potential infection and is not intended for long-term (>24 hours) use.

Components of the device are seen in **Figure 1** and described in **Table 1**. The device is comprised of a Bone Anchor, Cap, Cover, and optional Driver.

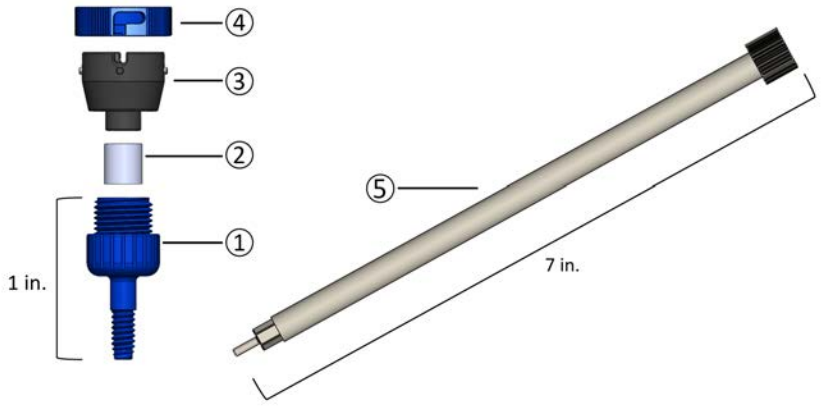

Figure 1. Package Contents. Refer to Table 1 for a description of each component.

Table 1. Bone Anchor component descriptions

No.	Description
①	Bone Anchor
②	Soft Silicone Seal (clear) – inside Bone Anchor
③	Compression Cap
④	Cover
⑤	Driver - optional

Package Contents:

REF **NGS-BA-01** **Bone Anchor**
Contents: Bone Anchors (1), Cap (1), Cover (1), Driver (1)

III. General Warnings and Precautions

WARNING STATEMENT	Indicates information regarding possible injury, death, or other serious consequences which could occur with use of the device.
CAUTION STATEMENT	Indicates information regarding possible minor harm or damage which could occur with use of the device.

WARNING: Prior to use, examine the product packaging and contents for damage, deterioration, and expiration date. Do not use the product if any of the parts of the device or the packaging is damaged, or if the product is expired.

WARNING: All tools, ancillary equipment and devices must be MR compatible when the Bone Anchor is used in a MR scanner. When labeling is unclear, assume the device is not compatible. Always follow the manufacturer's instructions.

WARNING: There are no known and reliable means of cleaning, disinfecting, repairing, and re-sterilizing the device that returns it to original specifications and renders it safe and effective for reuse. Infection or performance degradation may occur if the device is reused.

WARNING: To avoid potential exposure to blood-borne pathogens and chemicals, use appropriate personal protective equipment when handling or disposing of single-use devices.

WARNING: To prevent cross-contamination, always handle and transport devices that contact the central nervous system separately from other devices.

WARNING: Do not alter the product. Use the product only in accordance with its labeling.

WARNING: Abandon use of any device damaged during the procedure.

WARNING: Before attaching the Bone Anchor, carefully examine the patient image data to ensure that the skull thickness at the intended attachment site is adequate for securing the Bone Anchor. The skull thickness of the patient must be taken into consideration to avoid protrusion of the Bone Anchor into brain tissue.

WARNING: The Bone Anchor threads must engage with bone to ensure the device does not move relative to patient anatomy. If the device cannot be securely attached to the patient's skull for any reason, abandon use of the device.

WARNING: This device is intended for single patient use only. Contents of unopened, undamaged packages are sterile.

WARNING: Minimize exposure of the Bone Anchor and the inserted device to external forces after it has been placed.

WARNING: Use device with compatible Stereotactic Navigation System (SNS).

CAUTION: The compatibility of instruments and devices with the Bone Anchor should be evaluated before use.

CAUTION: Devices should be held from the point of insertion into a stereotactic frame or bone anchor until the device contacts the brain to prevent the device from advancing in an uncontrolled manner that could result in injury.

CAUTION: Handle all components using standard hospital sterile practices.

IV. Use Instructions

1) Align to the desired trajectory using a commercially available Stereotactic Navigation System (SNS).

   CAUTION: Prior to drilling, the angle between the skull and the planned trajectory must be verified. This angle must be large enough to minimize any slip of the drill and to provide enough clearance for insertion of the Bone Anchor.
2) Through the aligned SNS, create an access hole using a 3.2-3.4mm drill bit.

3) Mount the Bone Anchor by screwing it clockwise into bone until it is tight. This may be accomplished using one of two methods:

   a. Method 1, Bone Anchor as a Fixation Device:
      i. Place the compression Cap on top of the Bone Anchor and turn the Cap 2-3 times clockwise to secure it, as shown in **Figure 2**. Do not screw the Cap fully onto the Bone Anchor.
      ii. The assembled Bone Anchor and Cap may be passively loaded onto the compatible device held by the SNS prior to device insertion. The compatible device is then inserted to the intended target using the SNS, followed by manually securing the Bone Anchor into bone.

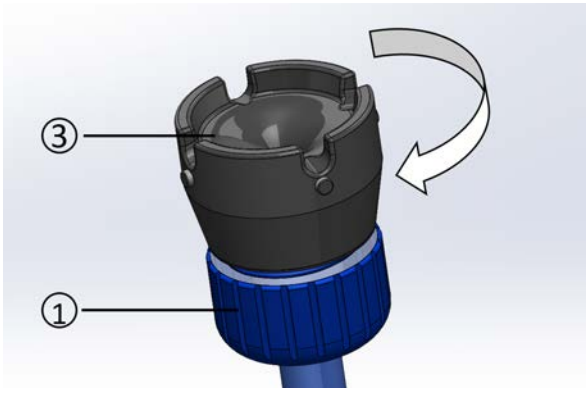

Figure 2. Deploying the Cap ③ onto the Bone Anchor ① by turning it clockwise. Do not screw Cap fully onto the Bone Anchor.

b. Method 2, Bone Anchor as a Trajectory and Fixation Device:
    i. The Bone Anchor may be mounted into bone prior to device insertion. The Driver is inserted through an appropriately sized guide within the SNS (reference **Table 2**). The Driver is then placed into the top of the Bone Anchor, as shown in **Figure 3**. Subsequently, the Bone Anchor is secured into bone by turning the Driver clockwise. The Driver is then removed.

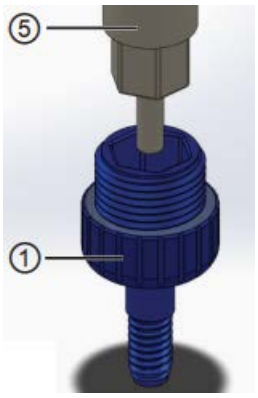

Figure 3. Mounting the Driver ⑤ into the Bone Anchor ①.

CAUTION: After mounting the Bone Anchor with the Driver, verify that the clear Soft Silicone Seal remains inside the Bone Anchor.

    ii. Place the Compression Cap on top of the Bone Anchor and turn the Cap 2-3 times clockwise to secure it, as shown in **Figure 2**. Do not screw the Cap fully onto the Bone Anchor.
    iii. A compatible device is then inserted to its intended target through the SNS and Bone Anchor.

WARNING: A clean drill hole with the correct hole size and no interference (e.g., caused by bone plates) is required to ensure an appropriate attachment point for the Bone Anchor to the skull. An inadequate drill hole could cause damage to the device, device instability, or detachment from the skull.

CAUTION: Verify the trajectory with SNS prior to device insertion. The drill hole should be aligned with the planned trajectory as the internal channel of the Bone Anchor will impact the inserted device's trajectory.

CAUTION: Do not over-tighten the Bone Anchor. Use caution when mounting the Bone Anchor, as over-insertion can lead to device breakage or advancement past the bone (skull) boundary. The Bone Anchor should not contact the dura mater nor central nervous system (CNS).

4) Hand-tighten the Cap to secure the device. The visible gap between the Bone Anchor and the Cap is small when tight, approximately 1.5mm (0.06").

5) If the surgical instrument or accessory is flexible per its labeling, the device may optionally be placed into one of the four slots within the compression Cap (**Figure**). The Cover may then be placed over the Cap and twisted clockwise to lock into place.

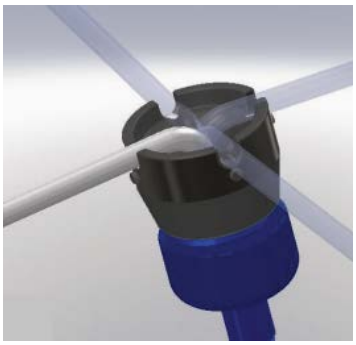

Figure 4. Flexible surgical instruments or accessories may be placed into one of the four slots within the Cap.

Bone Anchor Removal

6) If applicable, remove the Cover and lift the surgical instrument or accessory from the slot in the Cap.

7) Loosen the Cap, and carefully remove the surgical instrument or accessory from the brain.

8) Once completely out of the brain, remove the Bone Anchor from the skull. This may be done manually or with the Driver.

Disposal

9) Dispose of used devices and packaging in accordance with the facility and / or local government policy.

V. Storage and Technical Specifications

A. Storage

Store in a cool dry place according to product labeling.

B. Duration of Use

The device is designed for short-term use (< 24 hours).

C. Technical Specifications

Nominal dimensions for various components of the device are seen in **Table 2**. Error! Reference source not found. shows nominal dimensions of the Bone Anchor.

Table 2. Component specifications and dimensions

Bone Anchor, length (Error! Reference source not found.)	mm	25.4
	in	1
Bone Anchor, threaded length	mm	7.9
	in	0.31
Bone Anchor, travel per rotation	mm	0.84
	in	0.033
Bone Anchor, working lumen size	mm	2.2
	in	0.087
Drill bit compatibility	mm	3.2 to 3.4
	in	0.126 to 0.134
Driver, total length (Error! Reference source not found.)	mm	177
	in	7
Driver, outer diameter	mm	7.9
	In	0.31

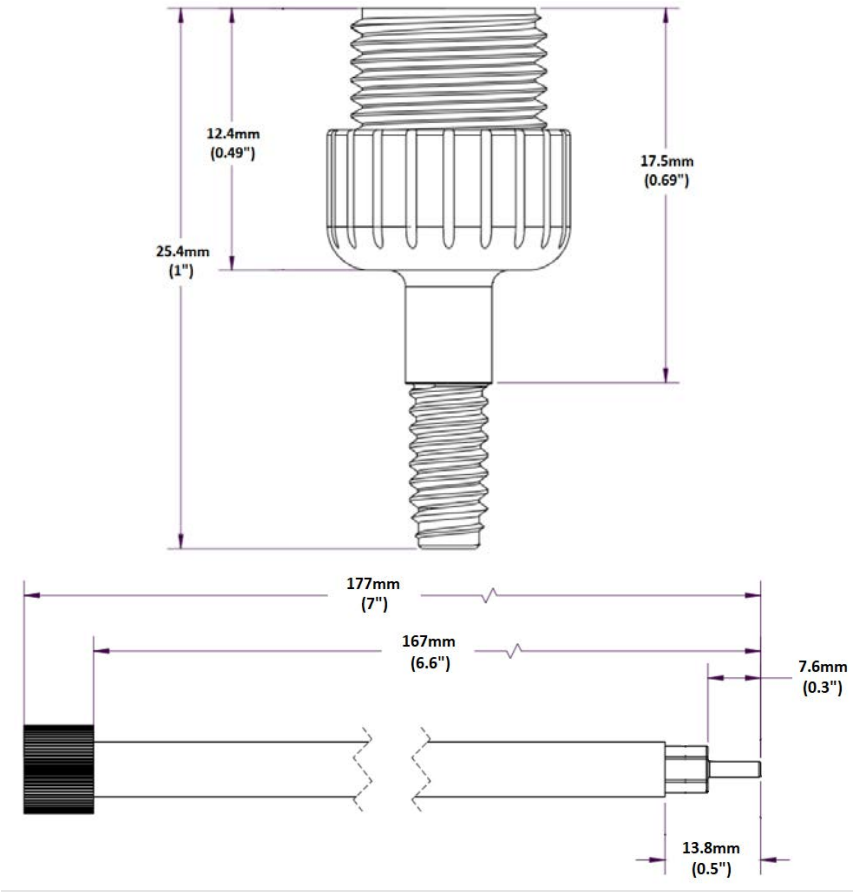

Figure 4. Nominal dimensions of the Bone Anchor (top) and Driver (bottom).

Explanation of symbols on product or package labeling - Refer to the appropriate product for symbols that apply.

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	MR Safe		Sterilized through irradiation
	Consult instructions for use		Manufacturer
	Catalogue number		Prescription Device
	Batch code		Keep dry
	Use by date		Keep away from sunlight
	Non-pyrogenic		Single use
	Double sterile barrier system		Not made with natural rubber latex
	Do not use if the product sterilization barrier or its packaging is compromised		

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