

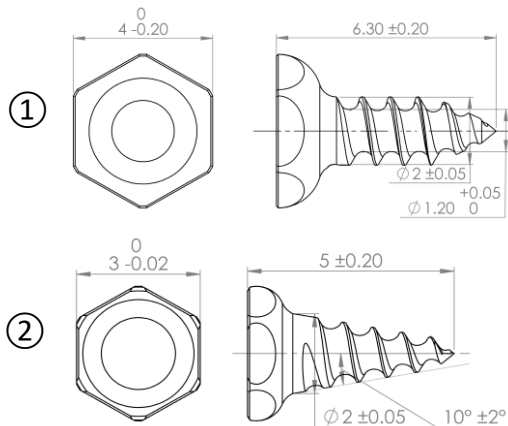
CRYPTYCH

INSTRUCTIONS FOR USE PRECISION SCREW

Rx Only

Product Description

No	Product Name	Product Code	Model Number
1	Precision Screw	CRY-01	CRY01-H4-1E
2	Precision Screw	CRY-01	CRY01-H3-1E



The Cryptych Precision Screw is a Ti6Al4V ELI metallic bone screw, of 2 mm diameter available in the following sizes:

1. 4 mm hexagonal head, 6.3 mm overall length
2. 3 mm hexagonal head, 5 mm overall length with a tapered shaft

The Precision Screw is designed to be inserted into cortical bone of vertebrae, and provide physicians with a tool to assist in the electromagnetic tracking of instruments with respect to pre-acquired or real-time image data.

The Cryptych Precision Screw is MR Safe.

The Precision Screw is to be inserted into bone using the Cryptych Precision Screw Driver. Consult separate instructions for use for the Precision Screw Driver (Product Code: CRY-02) prior to use.

Caution: Use of other drivers is not recommended. The Precision Screw Driver has been designed and tested purposefully for use with the Precision Screw.

Indications

The Precision Screw is intended for establishing one or more fixed reference point(s) in the vertebrae of patients while undergoing Stereotactic Surgery. The Precision Screw is used as an accessory with frameless navigation systems and their navigation probes.

Warning and Cautions

- 1) The screw is not intended for permanent implantation.
- 2) Avoid introducing particulate contaminants onto the implant surface during implantation or pre-operative handling. In addition lint, fingerprints, talc and other surface contaminants or residues from latex gloves can cause foreign body or allergic reactions.
- 3) Preoperative and operative procedures, including knowledge of surgical techniques, good exposure and proper placement of the implant are important considerations in the successful utilization of the Precision Screw.
- 4) There is potential risk for neurologic injury during placement of screws, either with the nerve (cauda equina) or spinal cord injury when placing them in the lamina, or traversing nerve root injury when placing these in the transverse process. Surgeon care should be exercised in selecting the insertion site to have sufficient bone thickness and away from the surgical site.
- 5) The Precision Screw should not be placed in the lamina where there is risk of traversing the lamina and perforating the dura which may lead to loss of Cerebral spinal fluid (durectomy). In these cases the screw should be placed in more bulky anatomic features, such as the spinous process and the vertebra. This also mitigates any risk of pseudarthrosis.
- 6) When removing the Precision Screw, care must be taken in re-engaging the driver to the screw to ensure minimal force is applied. The screw can be removed with other surgical tools, as deemed necessary by the surgeon.
- 7) The Precision Screw is not intended to be used for fixation or to bear load once implanted.
- 8) Placement of the screw the pars interarticularis may lead to fracture and is to be avoided.
- 9) Do not re-use.
- 10) Do not re-sterilize.
- 11) Do not use this device for any actions for which it was not intended.

Contraindications

Contraindications include, but are not limited to:

1. Active infectious process or significant risk of infection.
2. Signs of local inflammation.
3. Conditions which tend to limit the patient's ability or willingness to cooperate and follow instructions during the healing period.
4. Suspected or documented metal allergy or intolerance. Where material sensitivity is suspected, perform appropriate tests to rule out this possibility prior to implantation.
5. Any patient having inadequate tissue coverage over the operative site site or insufficient quantity or quality of bone to securely anchor the implant.
6. Any degenerative disease whose progress would adversely affect the placement of an implant.
7. The Precision Screw is not to be inserted in patients with compromised bone quality such as advanced Osteoporosis .
8. Any patient unwilling to follow postoperative instructions.

Directions for Use

1. Within this package are detachable labels that may be affixed to the medical record of the patient.
2. Prior to beginning the procedure, verify the overall compatibility of all instruments and accessories.
3. Inspect the device packaging prior to opening. The contents of the package are sterile if the packaging has not been compromised. If the package is damaged or it has been opened but the device not used, return the device and packaging to CRYPTYCH. Do not attempt to re-sterilise.
4. Remove the device from the package and place it in a sterile work area using aseptic technique.
5. Having exposed the desired levels of the vertebrae, the Precision Screw can be implanted into sufficiently thick bone of the vertebra, so that its threaded shaft is wholly within the bone. Examples of appropriate parts of the vertebra to receive the Precision Screw are the Transverse Process, the Spinous Process and the Lamina where it is sufficiently thick.
6. When implanting into hard/dense bone, ensure that a pilot hole is drilled prior to implantation.
7. During insertion, ensure that the screw is as close to perpendicular to the bone surface as possible.
8. Following implantation the head section of the screw should remain visible and accessible, but should not impede the conduct of the surgery.
9. The Precision Screw will provide a fixed reference point for images produced with CT and O-Arm imaging techniques. Navigational Systems using these imaging technologies must be selected. An example of such a device is the Medtronic O Arm Mobile CVT Device using the Medtronic Stealth Equipment and Software.
10. After imaging, the navigation probe may then be located in the screw head to confirm accuracy of navigation
11. The Precision Screw is not intended for permanent implantation and must be removed after use.



A coronal view of a vertebrae showing recommended areas for Precision screw insertion is provided in black



A transverse view showing recommended areas for Precision Screw insertion represented by black lines

Precautions

This device should only be used by physicians familiar with the device, its intended use, any additional instrumentation and available surgical techniques. Prior to use, read and follow the instructions of this insert, as well as those of the instruments to be used during the procedure. The operational state of all instruments should be reviewed regularly, and if necessary, the appropriate repair and replacement services utilised.

Potential Adverse Events

1. Breakage of the device, which could make necessary removal difficult or sometimes impossible, with possible consequences of infection.
2. Early or late loosening of the device.
3. Infection.
4. Foreign body reaction to implants, debris, corrosion products.
5. Tissue damage caused by improper positioning and placement of implants or instruments.
6. Change in mental status.
7. Adverse effects associated with spinal surgery including paralysis, sensory loss, loss of bowel and/or bladder control, failure of bone to incorporate, scarring of nerve roots.
8. General surgery complications from anaesthesia, infection, haematoma and death.

Packaging

Packages for all devices should be intact upon receipt. All products should be carefully checked for damage prior to use. Damaged packages or products should not be used, and should be returned to CRYPTYCH.

Sterilisation

The Precision Screw has been sterilised using Ethylene Oxide and designed for single patient use only. Do not re-use this product. Re-use may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness or death.

Storage and Handling

Sterile, packaged products should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.

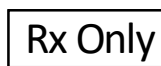
All products and packaging should be treated with care. Improper use or handling may lead to damage, improper functioning of the device or non-sterility.



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Australia
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Emergo Europe
Prinsessegracht 20, 2514 AP
The Hague, The Netherlands



Caution: US Federal law restricts this device to sale, distribution and use by or on the order of a physician.



Sterilised by Ethylene Oxide



Caution, Consult Instructions for Use



Lot Number



Use-by Date



Do not reuse



Do not re-sterilise



Date of manufacture



Do not use if package is damaged

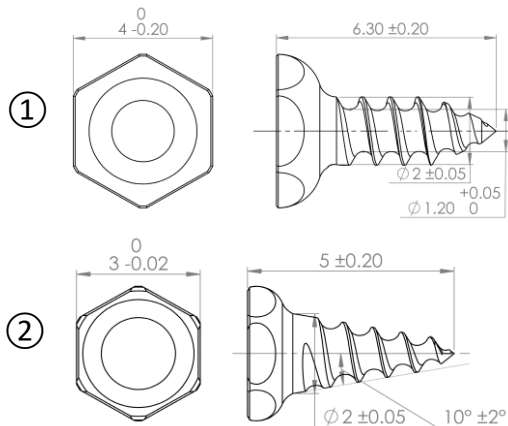
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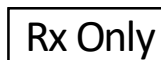
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Caution: US Federal law restricts this device to sale, distribution and use by or on the order of a physician.



Irradiation Sterilised



Caution, Consult Instructions for Use



Lot Number



Use-by Date



Do not reuse



Do not re-sterilise



Date of manufacture



Do not use if package is damaged