# CRYPTYCH

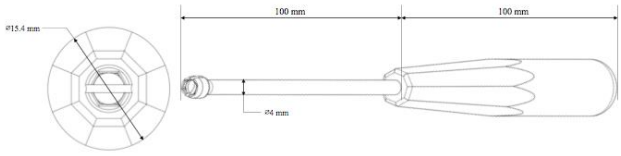
# INSTRUCTIONS FOR USE
# PRECISION SCREW DRIVER

Rx Only

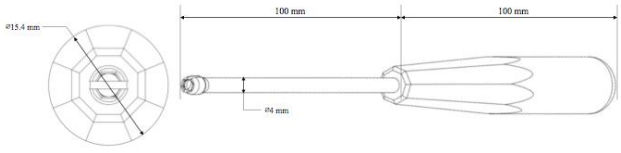
## Product Description

| | Product Name | Product Code | Model Number |
|---|---|---|---|
| ① | Precision Screw Driver | CRY-02 | CRY02-H4 |
| ② | Precision Screw Driver | CRY-02 | CRY02-H3 |

①




②




The Cryptych Precision Screw Driver is a stainless steel screw driver available in the following sizes:

1. 4 mm hexagonal head, 200 mm overall length
2. 3 mm hexagonal head, 200 mm overall length

The Precision Screw Driver is intended to drive the Cryptych Precision Screw into the vertebral cortical bone. Consult the separate instructions for use for the Precision Screw (Product Code: CRY-01) prior to use. The Precision Tray is intended to provide a location in which to store the Precision Screw Driver during surgery. Additionally, the Precision Tray provides a method for maintaining the dimensions of the driver head Consult the separate instructions for use for the Precision Tray (Product Code: CRY-03) prior to use.

## Indications

The Precision Screw Driver is indicated for orthopaedic surgical procedures of the spine, where the Precision Screw is to be used.

**Caution: This system is not intended to be used for fixation. The screw is not intended to bear load once implanted.**

## Warnings

New and used instruments **must** be thoroughly processed according to these instructions prior to use.

Care must be taken to ensure that particulate contaminants are not introduced onto components during handling.

Cleaning agents must be completely rinsed from device surfaces to prevent accumulation of detergent residue.

Dry soiled surgical instruments are more difficult to clean. Do not allow contaminated devices to dry prior to reprocessing.

Do not use this device for any actions for which it was not intended.

Saline and other irrigation fluids are often used in copious amounts during surgical procedures and may cause corrosion of instruments. **Do not use any instruments exhibiting signs of corrosion damage.**

## Precautions

This device should only be used by physicians familiar with the device, its intended use, any additional instrumentation and available surgical techniques. Read and understand all warnings, precautions and instructions before use.

The operational state of all instruments should be reviewed regularly, and if necessary, the appropriate repair and replacement services utilised.

During musculoskeletal surgery, instruments become contaminated with blood, tissue, bone fragments and marrow. The instruments may also become contaminated with body fluid containing etiological agents and pathogens. All healthcare workers should be familiar with the necessary precautions of preventing injuries when handling these devices during and after surgical procedures and during reprocessing.

Personal protective equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment.

Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments.

Cleaning agents with low foaming surfactants should be used during manual cleaning procedures. Manual scrubbing of instruments should always be performed with the instruments below the surface of the cleaning solution to prevent the generation of aerosols and splashing which may spread contaminants.

## Directions for Use

**Caution: Prior to use inspect Precision Screw (CRY-01) retention within the Precision Screw Driver (CRY-02). In addition, inspect the driver for damage and/or excessive wear. If the driver does not meet these functional requirements, or if damage or wear is noted that may compromise the function of the instrument, contact CRYPTYCH or their local approved sales agent for a replacement.**

1. Clean and sterilise the instrument prior to use, according to the validated procedures provided in the latest revision of DMR02-06.
2. Carefully inspect each driver to ensure that all visible contamination has been removed. If contamination is noted repeat the cleaning and disinfection process.
3. Prior to beginning the procedure, verify the compatibility of all instruments and accessories.
4. Remove the instrument from the package and place it in a sterile work area using aseptic technique.
5. Confirm the driver to be used is the correct size for the screw called for. The correct size screw will fit snugly into the driver without toggle.
6. Fit the screw squarely into the driver socket and pass to surgeon. The screw tip is then located on the area of bone to receive the screw and the driver rotated while steady pressure is maintained. In some cases of significantly hard bone a starter hole may be made with a burr or drill.
7. Continue advancing the screw until it is fully seated on the bone. Then withdraw the driver and confirm the screw is secure in the bone by direct palpation manually or with a probe or other such instrument.
8. When removing the screw, relocate the driver over the head, and turn the driver anti-clockwise until the screw is free of bone and soft tissue. Confirm that the screw is in the driver when it has been removed from the patient.

## Directions for Use (continued)

9. If the Precision Screw sits too loose in the driver head, or falls out when held vertically in the driver, place the driver into the appropriate re-dimensioning hole, to restore the head dimensions.
10. Thoroughly clean and sterilise the device after each use, according to the validated procedures provided in the latest revision of DMR02-06.

## Packaging

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

Sterile instrument packages should be carefully examined prior to opening to ensure that package integrity has not been compromised.

**Caution: Maintenance of sterile package integrity is generally event related. If a sterile wrap is torn, perforated, shows any evidence of tampering or has been exposed to moisture, the instrument set must be cleaned, re-packaged and re-sterilised.**

## Cleaning and Decontamination

Unless just removed from an unopened, sterile CRYPTYCH package, all devices must be unpackaged and cleaned prior to sterilisation and introduction into a sterile surgical field, or if applicable, return to CRYPTYCH.

The procedure, as given in the latest revision of Cryptych's Instructions For Re-processing Reusable Devices (DMR02-06), is to be followed for the cleaning and decontamination of the Precision Screw Driver prior to sterilisation.

## Sterilisation

Single devices should be packaged in a medical grade sterilisation pouch or wrap. Ensure that the pouch or wrap is large enough to contain the device without stressing the seals or tearing the pouch or wrap.

**Caution: If sterilisation wraps are used, they must be free of detergent residues. Reusable wraps are not recommended.**

Unless marked sterile and clearly labelled as such in an unopened sterile package provided by CRYPTYCH, all devices used in surgery must be sterilised prior to use. Remove all packaging materials prior to sterilisation. Only sterile products should be placed in the operative field.

Moist heat/steam sterilisation is the preferred and recommended sterilisation method, and the procedure given in the latest revision of Cryptych's Instructions for Re-processing Reusable Devices (DMR02-06) is to be followed.

The steriliser manufacturer's recommendations should always be followed. When sterilising multiple instruments in one cycle, ensure that the steriliser manufacturer's maximum load is not exceeded.

## Sterilisation (continued)

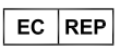
It is the responsibility of the processor to ensure that sterilisation is performed using equipment, materials and personnel that will achieve the desired results. This requires routine monitoring of the process. Any deviation of the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

## Storage and Handling

Ensure instruments are dry before storage. 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 should be treated with care. Improper use or handling may lead to damage and/or improper functioning of the device.

Cryptych Pty Ltd
Suite 1502, 275 Alfred Street
North Sydney NSW 2060
Australia
www.vestech.com.au




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.


Non-sterile

Consult Instructions for Use


Lot Number

Date of manufacture

Do not use if package is damaged