

CRYPTYCH

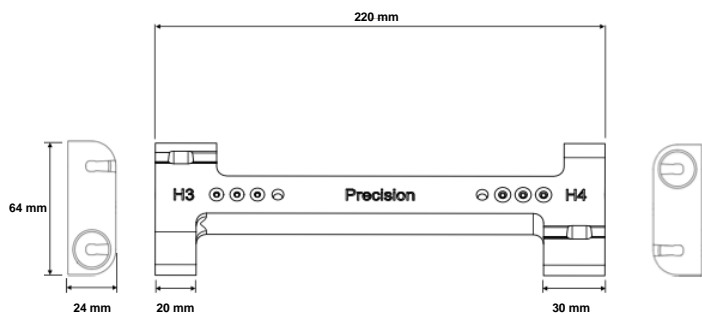
INSTRUCTIONS FOR USE

PRECISION TRAY

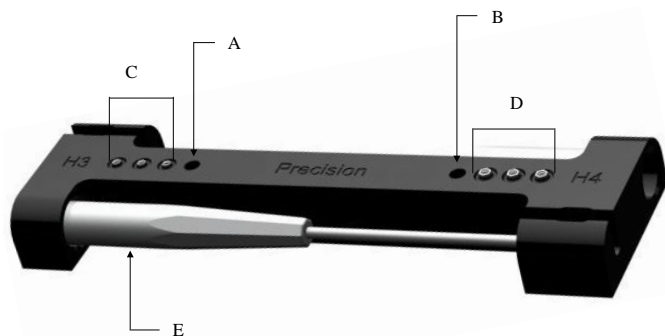
Rx Only

Product Description

Product Name	Product Code
Precision Tray	CRY-03



A	H3 Precision Screw Driver Dimension Check Hole
B	H4 Precision Screw Driver Dimension Check Hole
C	H3 Precision Screw Pockets
D	H4 Precision Screw Pockets
E	Precision Screw Driver Slot



The Cryptych Precision Tray is composed of acetal copolymer and is available in a single size.

The Precision Tray is intended to provide a location in which to store the sterile Cryptych Precision Screws and Precision Screw Drivers during surgery. Additionally, the Precision Tray provides a method for maintaining the dimensions of the driver head following multiple uses. Consult the separate instructions for use for the Precision Screw (Product Code: CRY-01) and Precision Screw Driver (Product Code: CRY-02) prior to use.

Note: Precision Screw (CRY-01) and Precision Screw Driver (CRY-02) are not included with Precision Tray.

Indications

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

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.

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.

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 the device.

Cleaning agents with low foaming surfactants should be used during manual cleaning procedures. Manual scrubbing should always be performed with the device 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 Tray for damage and/or excessive wear. If any damage or wear is noted that may compromise the function of the device, contact Cryptych or their local approved sales agent for a replacement.

1. Clean and sterilise the Precision Tray prior to use, according to the validated procedures provided in the latest revision of Instructions For Re-processing Reusable Devices (Doc ID: DMR02-06).
2. Carefully inspect the tray 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 with all associated devices.
4. Remove the tray from the package and place it in a sterile work area using aseptic technique.
5. Place the sterile Precision Screws in the appropriate holding positions on the tray.
6. Place the sterile Precision Screw Driver into the appropriate position on the tray.
7. When required for use, align the driver over the head of the corresponding screw. Load the screw squarely into the driver socket.
8. If the Precision Screw sits loosely in the driver head, or falls out when held vertically in the driver, place the driver into the appropriate driver hole to resize the head to the appropriate dimensions.
9. 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 Crytych.

Sterile device packaging 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 Crytych package, all devices must be unpackaged and cleaned prior to sterilisation and introduction into a sterile surgical field.

The procedure, as given in the latest revision of Crytych's Instructions For Re-processing Reusable Devices (Doc ID: DMR02-06), is to be followed for the cleaning and decontamination of the Precision Tray 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 Crytych, 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 recommended sterilisation method. The procedure given in the latest revision of Crytych's Instructions for Re-processing Reusable Devices (Doc ID: 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.

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.

Caution: Ensure that the Precision Tray is sterilised individually. The Precision Screw Driver (CRY-02) and any screws are to be removed from the Precision Tray prior to sterilisation.

Storage

Ensure product is 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.

Handling

All products should be treated with care. Improper use or handling may lead to damage and/or improper functioning of the device.

Disposal

The Precision Tray is a reusable and should be disposed as per Crytych's Instructions for Re-processing Reusable Devices (Doc ID: DMR02-06).

If required, to safely dispose of the Precision Tray following use, whilst wearing PPE, place the tray in the Hazardous Medical Waste (i.e., clinical waste) bin, in accordance with local procedures and guidelines for the disposal of infectious waste.

Serious Incident Reporting

If the device could have caused or contributed to the death or serious injury of a patient, user, or other persons, or a serious public health threat, Crytych must be notified immediately. These serious incidents must also be reported to the Competent Authority of the European Member State or, when applicable, the equivalent regulatory authority, where the user and/or patient is established.

Please decontaminate and retain any device and their packaging for return to Crytych for inspection.

For further information or for all other complaints, please contact Crytych:

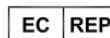
Tel: +61 2 9959 5820

Email: ComplaintManagement@vestech.com.au

The Competent Authority for each Member State can be found at https://ec.europa.eu/health/md_sector/contact_en



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Emergo Europe
Prinsessegracht 20, 2514 AP
The Hague, The Netherland



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