PRODUCT NAME ENDOGLIDE™ SUPPORT PLATFORM
PRODUCT INFORMATION, CLEANING AND MAINTENANCE INSTRUCTIONS AND INSTRUCTIONS FOR USE

Symbols Used

LOT GB- Lot Number	EC REP GB – EU Authorised Representative	NON STERILE GB- Non Sterile	GB- Do not use if product is opened or damaged and consult instructions for use	GB – Manufacturer	GB – Date of Manufacture
REF GB- Catalogue Number	GB- Caution	COR_012 GB - Consult Electronic Instructions for Use	℞only GB – Caution: United States Federal law restricts medical devices to sale by or on the order of a physician	MD GB – Medical Device	UDI GB – Unique Device Identifier

GB - INSTRUCTIONS FOR USE

Description
The **CORONET ® Support Platform** is useful to support the CORONET ® EndoGlide ™ or Donor Trephine Punch. The ergonomic design of the platform assists loading of the EndoGlide.

Intended Use
The EndoGlide Support platform is intended to provide a stable base to assist the loading of the EndoGlide.

Cleaning and Maintenance
These instruments are not delivered sterile; and consequently it is necessary to clean and sterilise them properly before use.
These instructions are intended for use by persons with the required specialist knowledge and training. All persons handling the platform should be knowledgeable in the use and handling of surgical instruments, accessories and related equipment.

CAUTIONS
- **If the product is opened or damaged, inspect under magnification for any possible damage to the instrument prior to use**
- **Instruments must be used for their specified purpose and incorrect use could damage the instrument.**
- **Incorrect handling and care, as well as misuse could damage the platform and lead to premature wear of the device.**
- **Care of the platform should begin as soon as you receive it.**
- **Each platform should be examined to ensure it has been received in perfect condition. If a problem is found on initial inspection, please notify Network Medical immediately.**
- **Once the platform has been accepted, it should be cleaned and sterilised before being used.**
- **Prior to sterilisation, visually inspect for any physical damage to the device, breaks, cracks, misalignments, scratches, etc. Any platforms that appear damaged must not be used.**
- **Care should be taken in the handling and disposal of the device after use to prevent contamination.**
- **Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Wherever possible avoid use of mineral acids and harsh, abrasive agents.**
- **No part of the process shall exceed 140°C.**
- **TAKE CARE** NOT TO DROP THE INSTRUMENT ONTO A HARD SURFACE as this will likely cause damage.

Note: When reprocessing medical devices, always handle with care, wearing protective clothing, gloves and eyewear in accordance with local Health & Safety procedures.

Incident Reporting
Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Limitations on Reprocessing
- Repeated **processing has minimal effect on the platform.**
- **The end of life is normally determined by the wear and damage in use. The life of a platform depends on the care given to it whilst it is being used, cleaned and maintained.**

Instructions
- Wherever possible, do not allow blood, debris or bodily fluids to dry on the instruments. For best results and to prolong the life of the medical device clean and reprocess immediately after use. If they **cannot** be reprocessed immediately, use an enzymatic foam spray cleaner to help prevent soil from drying.

We recommend that you strictly follow the instructions given below in order to guarantee the longevity of your instruments. The life of an instrument depends on the care given to it whilst it is being used, cleaned and maintained.

Preparation at point of use
- **Ensure staff who will be processing the devices are trained in handling the devices due to their delicate nature.**
- **Wherever possible do not allow debris (e.g. blood or other bodily fluids) to dry on the devices. For best results and to maximise instrument life, process as soon as is reasonably practical after use.**
- **Ensure** all instruments exposed during the surgery are reprocessed, even if they were not used as they may have been inadvertently contaminated.

Rinsing – post-op
- **Remove** excess soil by rinsing in pure water (below 40°C) as soon as possible after use.

Cleaning : Manual
1) Clean after final use by rinsing in distilled / sterile water before sterilising to remove any contaminants. Do not scrub or apply force.
2) After cleaning, the instrument should be carefully inspected under magnification for any possible wear or damage prior to sterilisation.

Cleaning : Automated
- **Load the instrument into it's own individual sterilising tray.**
- **Use only either CE marked or validated washer-disinfector machines and low-foaming, alkali or enzymatic cleaning agents and detergents following the manufacturers' instructions for use, warnings, concentrations and recommended cycles.**
- **Sonication** is permitted.

Cleaning : Inspection
After cleaning, visually inspect all surfaces and crevices for complete removal of soil and fluids. If ANY soil or fluid is still visible, return the instrument for repeat decontamination.

Inspection and Function Testing
- Visually **inspect and check all instruments for damage and wear.**
- **Remove for repair or replacement any fractured or damaged instruments.**

Note: If an instrument is returned to the manufacturer / supplier, the instrument **must** be decontaminated and sterilised and be accompanied by the relevant documented evidence.

Sterilisation
- Ensure all **instruments are thoroughly cleaned before sterilising**
- **Place the instrument in an individual perforated sterilising tray.**
- **The packaging of the instruments must be suitable for steam sterilisation e.g. single or double paper / foil sterilisation packaging.**
- **Follow local** protocols to applicable regulatory guidance for autoclave sterilization. Network Medical have validated the following autoclave protocol as shown below:.

Autoclave Prevacuum (dynamic air	Autoclave	CE marked and maintained to applicable regulatory guidance
	Water	Pure water

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removal) sterilization cycle or gravity sterilization cycle.	Holding Time (E.g. Sterilization time)	3 to 3½ minutes
	Sterilization temperature	134°C to 137°C 273.2° F to 278.6°F
Load the autoclave as described in the autoclave manufacturer's instructions for use, do not overload.		
Ensure the autoclave has fully finished the cycle before opening the door. Failure to do so may result in wet product. All product and packaging must be dry when the autoclave cycle has finished. If not, they should be reprocessed and the autoclave reviewed for suitability.		

Storage
Ensure instruments are dry before storage, and stored in dry, clean conditions at an ambient room temperature.

NOTE:
- **These instructions have been validated to ISO 17664 Sterilisation of Medical Devices – Information to be provided by Manufacturer for the processing of Resterilisation medical devices.**
- **It is the responsibility of the reprocessor to ensure that the reprocessing as actually performed using equipment; materials and personnel in the reprocessing facility achieve the desired result. This requires validation and routine monitoring of the process.**
- **Any deviation by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.**

Warnings including association of use of reusable surgical instruments with occurrence of CjD & vCjD.:
- There **is a risk of cross-contamination and infection risks to patients including transmission of CJD & Variant CJD.**
- **Follow hospital/facility approved procedures or recommendations in "Transmissible Spongiform Encephalopathy Agents: Safe Working And The Prevention Of Infection" compiled by the Advisory Committee on Dangerous Pathogens Spongiform Encephalopathy Advisory Committee for processing devices that have been exposed to unconventional slow viruses or prion diseases such as Creutzfeldt Jakob Disease (C.J.D), Kuru, Gerstmann-Straussler-Scheinker Syndrome (G.S.S.), Fatal Familial Insomnia (F.F.I.), Scrapie, Bovine Spongiform Encephalopathy (B.S.E.) etc.**
- **Segregate instruments** used on high risk tissues for patients born after 1st January 1997. See NICE IPG 196 (2006)

Warnings including association of use of instruments with occurrence of Toxic Anterior Segment Syndrome (TASS)
- **Residuals** from cleaning agents not removed during the cleaning process can be one of the causes of TASS. Follow these instructions explicitly when using, decontaminating and cleaning and sterilising the platform.

This IFU is available in other languages upon request. Please contact Network Medical Products Limited for details.

PRODUCT DETAILS **Cat Ref:**	**Description**
53-920	EndoGlide Support Platform

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