



Sterile Single Use Needle Holder Instructions for Use

Sterile Single-Use Manual Needle Holders Intended Use

Sterile single-use manual Needle Holders are intended for use in multiple surgical specialties to perform basic surgical tasks such as manipulating and grasping needles.

Indications For Use

A needle holder, also called needle driver or needle forceps, can be used to hold and push a suturing needle when performing wound closure, ligation and other surgical procedures that require re-anastomosis. It is the responsibility of the surgical team to select the appropriate instrument for each case.

Materials

The Needle Holders consist of the following patient contacting materials: stainless steel

Contraindications

None known.

Pre-use/Handling/Inspection

- Check the packaging for damage which can compromise sterility.
- Dispose of the sterile single-use Needle Holders in accordance with all applicable federal, state and local medical and hazardous waste practices.
- Do not reuse or re-sterilize single use devices

Warnings

- Do not Reuse Single-Use Devices.
- Do not re-sterilize sterile packaged devices
- Do not use these instruments for purposes other than those for which they are intended.
- Do not allow conductive instruments to contact active cautery devices, or use in current paths, as patient or user burns may occur.
- Do not bend, pry, or use excessive force; breakage or failure of the instrument could occur resulting in possible harm to the patient or user.
- Use extreme care during handling of delicate or sharp instruments as injury or damage could occur.
- Use appropriate personal protection equipment when handling contaminated instruments.

Troubleshooting And Repairs

Fremantle Stainless disclaims all responsibility in cases of improper user handling or unauthorized repairs.

Returns

Contact Phoenix Surgical Supplies to obtain a Return Goods Authorization number (RGA#) prior to shipping the product back to Fremantle Stainless. The RGA# should be prominently displayed on the outside of the return packaging and included on all paperwork enclosed with the return. All product returned should be decontaminated and cleaned, and all products should be safely packed in protective wrapping. Please have the original invoice number or purchase order number available to assist in verifying warranty information.

Customer Service Information

For further information regarding the use of this product or to report any problems, please contact Phoenix Surgical Supplies on 08 6311 2885

Limited Warranty

- A. This LIMITED WARRANTY provides assurance for the customer who purchases a Fremantle Stainless Product (hereinafter the "Product") that should the Product fail to function to Fremantle Stainless' published specifications during the term of this LIMITED WARRANTY (one year from the date of shipment for new Product), Fremantle Stainless will either replace, repair, or issue a credit (adjusted to reflect the age of the Product) for the Product or any portion thereof. This LIMITED WARRANTY is extended only to the buyer purchasing the Product directly from Fremantle Stainless or from its affiliate or its authorized distributor or representative.
- B. To qualify for this LIMITED WARRANTY, the following conditions must be met:
- (1). The Product must be used on or before its "Use By" or "Use Before" date, if applicable.
 - (2). The Product must be used in accordance with its labelling and may not be altered or subjected to misuse, abuse, accident or improper handling.
 - (3). Fremantle Stainless must be notified in writing within thirty (30) days following discovery of a defect.
 - (4). The Product must be returned to Fremantle Stainless within thirty (30) days of Fremantle Stainless receiving notice as provided for in (3) above.
 - (5). Upon examination of the Product by Phoenix Surgical, Fremantle Stainless shall have determined that:
 - (i) the Product was not repaired or altered by anyone other than Fremantle Stainless or its authorized representative,
 - (ii) the Product was not operated under conditions other than normal use, and
 - (iii) the prescribed periodic maintenance and services have been performed on the Product.
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