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| <p><b>General:</b></p> <p>HAAS guidewires may only be used by doctors familiar with the product, its application and possible complications. The guidewires may only be used in hospitals where immediate emergency intervention can be carried out in the event of injury or potentially life-threatening complications.</p> <p><b>Design:</b></p> <p>Guidewires with a straight or J-tip, PTFE or uncoated, with a fixed or movable core in various lengths and diameters. Please refer to the label for specific information on the design and dimensions of the guide wire.</p> <p><b>Indications:</b></p> <p>HAAS guidewires are used to guide interventional catheters with compatible lumens in the peripheral circulatory system.</p> <p>The HAAS-PTA guidewires are designed to facilitate the placement of balloon dilation catheters with compatible guidewire lumens in percutaneous transluminal coronary angioplasty (PTCA).</p> <p><b>Contraindication:</b></p> <p>Guidewires with a diameter of &gt; 0.014" (0.36 mm) may present chronic total occlusions (CTOs). Further contraindications and possible complications are indicated in the instructions for use of the interventional catheter or other products used with the guidewire and must be observed.</p> <p>The HAAS guidewires are not designed for use in the central circulatory system, or in cardiac or cerebral blood vessels.</p> <p><b>Warnings:</b></p> <p>This product is only designed for single use and is sterile packed.</p> <p>The product may not be resterilized or reused, as contamination or infection cannot be ruled out during reuse.</p> <p>The product must be stored in a dry environment within the defined temperature range and protected from light. The product may no longer be used if the package or product is damaged.</p> <p>Guidewires are sensitive instruments and must be handled with care. Inspect the guidewire carefully for bends, kinks, or other damage prior to use and during the procedure. Do not use damaged guidewires, as this may result in blood vessel damage or inaccurate torque response.</p> | <p>It is important to ensure that products not belonging to the guidewire are compatible, and that the instructions for use are followed.</p> <p>It is important to ensure that no guidewires can or do remain in the body unintentionally and unnoticed.</p> <p>Track the guidewire using X-ray fluoroscopy. Do not manipulate the guidewire without observing the resulting movement of the tip, as this could otherwise result in damage to blood vessels. Manipulation of a guidewire against resistance may cause guidewire damage or guidewire tip separation.</p> <p>A guidewire with a movable core may not be manipulated against a resistance.</p> <p>Guidewires contain metals and may not be used under MR fields, as they could otherwise be damaged and/or heat up.</p> <p><b>Possible complications:</b></p> <ul style="list-style-type: none"><li>- Air embolism</li><li>- Iatrogenic infection</li><li>- Organ or vessel spasm</li><li>- Organ or vessel lesions</li><li>- Organ or vessel dissection</li><li>- Organ or vessel perforation</li></ul> <p>The current medical standards must be observed.</p> <p><b>Handling instructions:</b></p> <p>Rinse the guidewires with physiological saline solution before removing them from the dispenser. Use aseptic techniques in handling the guidewire.</p> <p>The guidewire should be just over twice the length of the catheter, because this has to be gasped proximal or distal to the guided catheter.</p> <p>The guidewire may not be removed through a metallic cannula needle. The coating on PTFE-coated guidewires in particular may be damaged.</p> <p>After removing the guidewire from the body, it must always be wiped clean with gauze soaked in sterile heparinized saline solution and kept moist. Before reintroducing, only ever during the same procedure, check the guidewire again to ensure it is not damaged. Never reintroduce a damaged guidewire.</p> <p>Rinse the guidewire with sterile heparinized physiological saline solution before reintroducing a guidewire.</p> <p>After use, carefully dispose of the guidewire according to recognized methods and legal requirements.</p> <p>In the event of a product complaint, please send the guidewire to Carl Haas. A complaint form must also be submitted.</p> | <table><tr><td></td><td>Observe the user manual</td></tr><tr><td></td><td>Use by date</td></tr><tr><td></td><td>Catalog number</td></tr><tr><td></td><td>Batch code</td></tr><tr><td></td><td>Manufacturer</td></tr><tr><td></td><td>Keep away from sunlight</td></tr><tr><td></td><td>Store dry</td></tr><tr><td></td><td>Do not use if packaging is damaged</td></tr><tr><td></td><td>Do not resterilize</td></tr><tr><td></td><td>Do not re-use</td></tr><tr><td></td><td>Sterilized by irradiation</td></tr><tr><td></td><td>Temperature limit</td></tr><tr><td></td><td>Use under MR fields prohibited!</td></tr></table> <div><p>Carl Haas GmbH<br/>Dr.-Konstantin-Hank-Str. 18<br/>78713 Schramberg, Germany<br/>Tel. +49-74 22 567 0<br/>Fax +49-74 22 567 239<br/>E-Mail: <a href="mailto:medical@carl-haas.com">medical@carl-haas.com</a></p><div> 0297</div></div> |  | Observe the user manual |  | Use by date |  | Catalog number |  | Batch code |  | Manufacturer |  | Keep away from sunlight |  | Store dry |  | Do not use if packaging is damaged |  | Do not resterilize |  | Do not re-use |  | Sterilized by irradiation |  | Temperature limit |  | Use under MR fields prohibited! |
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