**General:**

HAAS-PTCA guidewires may only be used by physicians trained in angiography and percutaneous transluminal coronary angioplasty (PTCA) and who are familiar with 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.
Please always observe the indications, contraindications and possible complications stated in the user guides of any interventional products used in combination with PTCA guidewires.

**Design:**

The HAAS-PTCA guidewires are steerable and have a diameter of 0.014“ (0.36 mm) and a length of between 175 cm and 190 cm. The distal section of the guidewire is about 30 mm long and is shapeable and radiopaque. The proximal coiled end is slightly radiolucent. The guidewires are available in five designs with varying degrees of distal rigidity:

High Floppy (HF), Floppy (F), Medium (M), Stiff (S) and High Stiff (HS). Increased rigidity in the medial and proximal areas of the coil in the STF type guidewire facilitates stent implantation.
Please refer to the label for specific information on the design and dimensions of the guidewire.

**Indications:**

The guidewires are designed to facilitate the placement of balloon dilation catheters with compatible guidewire lumens in percutaneous transluminal coronary angioplasty (PTCA).

**Contraindications:**

- Previously diagnosed, severe coronary artery spasms or arterial spasms.
- 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.
- This HAAS guidewire is not designed for use in cerebral blood vessels.

**Possible complications:**

- Air embolism
- Iatrogenic infection
- Organ or vessel spasm
- Organ or vessel lesions
- Organ or vessel dissection
- Organ or vessel perforation

The current medical standards must be observed.

**Warnings:**

This product is only designed for single use and is sterile packed.
The product may not be resterilized or reused, as contamination or infection cannot be ruled out during reuse.

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.

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.

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.**

Guidewires contain metals and may not be used under MR fields, as they could otherwise be damaged and/or heat up.

**Handling instructions:**

Use aseptic techniques in handling the guidewire. Observe the user manuals of all interventional products used with the guidewires. Before the interventional procedure carefully examine all products to be used for defects. Do not use faulty products.

1. Before removing the guidewire from the dispenser, inject a sterile heparinized physiological saline solution into the Luer lock element of the dispenser to moisten the entire surface of the guidewire.
2. To remove the guidewire from the dispenser, carefully withdraw the protruding proximal end of the wire.
3. If necessary, the guidewire tip can be carefully shaped according to standard techniques to form a tip. Do not use sharp shaping instruments.
4. Prepare the interventional product according the manufacturer's instructions. Flush the guidewire lumen before introducing the guidewire.

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. Rinse the guidewire with sterile heparinized physiological saline solution before reintroducing a guidewire.

After use, carefully dispose of the guidewire according to recognised methods and legal requirements.

In the event of a product complaint, please send the guidewire to CARL HAAS. A complaint form must also be submitted.

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|  | Observe the user manual |
|  | Use by date |
|  | Catalogue 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 limits |
|  | MR unsafe |

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