Instruction for Use
hydrophilic coated Nitinol Guide Wires SU "Smart-Guide" and "Hi-Flex"

Attention:
This medical device may only be purchased by specialists, doctors and medical personnel and may only be used in accordance with these instructions for use and the defined area of application.

Description/Variants
Nitinol guide wires consist of a Nitinol core, a flexible to highly flexible plastic tip (straight or curved) and a coloured plastic coating (violet-white and violet-yellow) with extremely high sliding properties. Distally, these are equipped with a hydrophilic coating. For protection and better handling, the wires lie in a ring-shaped plastic dispenser. These wires are available in the diameters .025" and .035" with a length between 300 cm and 600 cm.

Products
This user manual is valid for the products listed below:
- 21635450 "Smart-Guide"
- 21725450 "Hi-Flex"
- 21735450 "Hi-Flex"
- 21735600 "Hi-Flex"
- 21825450 "Hi-Flex"
- 21835450 "Hi-Flex"

Important Note
Please ensure you read this user manual carefully before each use and keep it somewhere that is easily accessible for users and/or appropriate specialist staff.

⚠ **Ensure you carefully read through the warnings indicated by this symbol. Patients, users or third parties may suffer serious injury as a result of the improper use of the products.**

Content and Packaging
Nitinol Guide Wires SU are offered in packaging units of 1 pieces:
- 1 outer box
- 1 Nitinol Guide Wire SU (**S**ingle **U**se) incl. individually sterile packed
- 1 Instructions for use

Patient Population
The patient population or target patient group is derived from the indication determined by the responsible doctor who diagnostically or therapeutically treats the patient as part of an endoscopic procedure (the leading procedure per se) according to the intended use of the medical device.
There are no known restrictions to the patient population or the target patient group.
- **Use of the product on minors:**
  The user can use the product on minors in the case that the physiological and anatomical conditions of the patient permit the use of the product.
- **Use of the product on women who are pregnant or breastfeeding:**
  The indication for the use of the product on women who are pregnant or breastfeeding must be narrowed down by the user based on the respective individual physiological and anatomical conditions of the patient.

1. Scope of Application
The products listed above must only be used by physicians with appropriate specialist training in gastroenterology. The products are intended solely for the medical sector as illustrated below and must therefore be used within an operating environment suitable for this purpose. It is essential that both the user as well as the appropriate specialist staff familiarize themselves with the instruments before the user makes use of them.

2. Application Period
The Nitinol Guide Wires are intended to be used uninterrupted for a period of less than 60 minutes under normal conditions (MDD 93/42 EEC).

3. Intended Use
Guide Wires are intended to be used in natural or surgically invasive orifices as a guidance for introduction and placement of diagnostic or therapeutic devices in hollow organs of the human body during endoscopic or interventional procedures. Such procedures are gastroenterological procedures.
Indications
- ERCP
- all kinds of endoscopic interventions in the gastroenterology tract

Contraindications
As the guide wire is only an accessory for the above mentioned indications the contraindications are limited to the contraindications for these applications.
- Cerebral vascular intervention,
- Central circulation system,
- Guide wires with polymer tip shall exclusively be inserted via natural pathways and not in the vascular system, and by no means surgically invasive, due to the risk of fragmentation via the corresponding, mostly metallic accesses.

4. Risks and Side Effects
Sedation during endoscopic examination increases the risk of hypoxemia, hypercapnia, hypotension, arrhythmias and aspiration due to reduced protective reflexes. Hypoxemia also occurs without sedation during endoscopic examinations due to the feed of the endoscope.

⚠ **Appropriate preparations for complications that may arise must be made prior to use!**

5. Shelf Life of Products
The shelf life of the product is typically 3 years after the date of manufacture under normal conditions.

6. Function Test
The medical devices must be checked with regard to the following aspects prior to use:
- Expiration date
- Undamaged packaging
- Damage on the product (cracks, bending, deformation)

Inspect products for immaculate surfaces, correct assembly and functionality.

Products that have failed the function test must not be used as their sterility and product safety cannot be ensured. Dispose of these products accordingly, or please return them to the manufacturer.

7. Application
General
The application of the product is exclusively restricted to medical specialists and experienced users.
The interventional combination device has to be prepared according to the instructions of the manufacturer of the device. The guide wire lumen of the combination device has to be flushed before insertion of the guide wire.
Guide Wires with Hydrophilic Coating
Prior to the withdrawal of the full length hydrophilic guide wire from the dispenser, physiological saline solution has to be injected into the hub end of the dispenser in order to wet the complete hydrophilic surface of the guide wire.
After the injection of the saline solution, the guide wire has to be carefully withdrawn from the dispenser. If the guide wire cannot be easily withdrawn from the dispenser further saline solution has to be injected into the dispenser. After withdrawal, the guide wire must not be introduced into the dispenser again.

8. Warning Notice
If not used correctly guide wires can lead to perforation of tissue. The damages caused by perforation may be serious and can lead to death of the patient. Tissue perforation primarily occurs due to kinking of the guide wire. During the use of guide wires an insertion technique must be used that avoids kinking of the guide wire. An insertion guide has to be used. Furthermore, there have been cases of overinsertion of guide wires; this is generally considered a serious risk. Overinsertion of guide wires can lead to injury and/or perforation of the vessel being treated.
Guide wires contain magnetizable materials and must therefore not be used with MRI, as heating and movement of the guide wire can occur due to the existing residual magnetism, which may lead to severe complications.

⚠ **These guide wires must not be with MRI!**

According to clinical data found in literature, a passing through strictures greater than 1 cm in length may lead to damage or breakage of soft guide wires. This should be taken into consideration during surgical planning. In rare cases, repeated leading back and forth of the guide wire may lead to knot building at the distal tip of the wire. Therefore, the user should have appropriate knowledge in such techniques in order to manage serious complications related to such events. If coated guide wires are used with other medical devices (e.g. catheter), special attention has to be paid to an appropriate combination to avoid damages to the integrity of the coating. Certain cases of entrapped or breakdown guide wires have been reported as well as possible techniques to retrieve the entrapped or broken parts. The user should have knowledge in such techniques in order to prevent serious consequences related to such events. Like almost every product that is introduced into blood vessels, guide wires may lead to thrombosis. The user is responsible for taking adequate measures to prevent thrombosis during the application of the guide wire. The guide wire should be manipulated slowly and carefully. The behavior and advancement of the guide wire tip should be controlled under fluoroscopy. Manipulation of the guide wire without control by fluoroscopy can result in injury to the patient. The guide wire must be held in position when changing or withdrawing the catheter in order to prevent injury to the patient. Except special dedicated guidewires with measuring function, a scale on the guide wire or scaled radiopaque markers are for orientation only. The measuring results should be confirmed by other methods. If any resistance is felt during use, the manipulation of the guide wire and/or the combination device used such as catheter or endoscope must be stopped immediately and the cause for the resistance must be determined by use of various visual methods. Otherwise,

Instruction for Use
hydrophilic coated Nitinol Guide Wires SU "Smart-Guide" and "Hi-Flex"

overexpansion, kinking, breaks or partial detachment of the outer polymer jacket or the coating material of the guide wire can occur. Remove, if required, the guide wire and the combination devices used as a complete unit to avoid complications. Never insert, advance and/or withdraw the guide wire through a metal cannula or needle or other sharp-edged devices. This may damage the guide wire and may lead to destruction and/or detachment, in particular of the outer polymer jacket or the coating, and therefore may require subsequent retrieval of the fragments. Use extreme caution when using a device that emits energy (laser, pressure, ultrasound,...), and retract the guide wire into a position where it will not be damaged. Direct contact may cause damage to the wire and/or sever the wire.

9. Preventive Measures

- Guide wires are fragile devices which should be used very carefully. The device should only be used by experienced medical specialists. Furthermore, the application of the device requires a thorough understanding of the technical principles as well as the clinical applications and risks associated with the use of guide wires in order to avoid any damage to the guide wire and to prevent harm to the patient. Before and, if possible, during its use the guide wire should be checked visually for damages, misalignment, kinks, abrasions of the outer polymer jacket or the coating and for other deformations. Damaged, misaligned, kinked and other deformed guide wires must not be used any longer and must be discarded due to potential risk of tissue perforation. Likewise, guide wires with abrasions of the outer polymer jacket or the coating must not be used since this may cause detachment of polymer fragments from the guide wire.
- The compatibility between guide wire, particularly in case of guide wires with full length or partial hydrophilic coating, and interventional medical devices must be verified before use.
- Do not withdrawing the guide wire through a metal cannula. The sharp edges of the cannula can damage or shear the PTFE or polymer coating. The cannula should be replaced as soon as possible after the insertion of the guide wire into the vessel by a catheter, introducer sheath or vessel dilator.
- Due to variations in stiffness, inner diameter or shape of certain catheter tips, abrasions of the outer polymer jacket or the coating may occur when manipulating. If any resistance is felt during introduction of the catheter, such catheters should not be used.
- Guide wires with partial or full length hydrophilic coating must not come into contact with alcohol, antiseptic substances or substances containing solvents.

10. Reprocessing and Sterilisation

Guide wires are delivered in sterile condition. and **CANNOT EFFECTIVELY** be cleaned, disinfected and sterilised after single use on account of the design, as bodily fluids penetrate into the inner part of the wire, which can no longer be removed. Guide wires must be disposed of after single use.
The products are only sterile if the packaging is undamaged and unopened and if the shelf life is not exceeded. Products whose packaging is damaged or whose shelf life has expired must be discarded.

11. Disposal and Reprocessing

After use, this product may present a biological hazard. Handling and disposal must be carried out according to recognised medical procedures and in accordance with applicable legal requirements.
This guide wires are disposable products and must not be reprocessed and resterilized, as damage to the materials and the coatings cannot be ruled out.

12. Function Impairment

The instrument must be inspected for any damage along with its shelf life prior to use. Only non-damaged and sterile instruments may be used.

13. Liability and Warranty

As the manufacturer here, ENDO-FLEX shall not be liable for any damage or consequential damage arising from improper use or handling. This shall in particular apply to any use not in line with the defined purpose or failure to observe the preparation and sterilisation instructions and warnings. This shall also apply to repairs or modifications to the product made by individuals who are not authorised to do so by the manufacturer.

14. Service

Do not carry out any modifications to the product. If you have any concerns, complaints or comments regarding our products, please get in touch with us.

15. Transport and Storage Conditions

- Products may only be transported and stored in the packaging provided for this purpose.
- Products must be stored dry and protected from sunlight at room temperature.
- Do not place any objects on the storage packaging and the sterile barrier system!
- Ensure the instruments are not kept near to chemicals, disinfectants or radioactive radiation!

16. Symbols used

Symbol for "Item Number"

Symbol for "Batch code"


Symbol for "Manufacturer"


Symbol for "Date of manufacture"


Symbol for "Observe instructions for use"

Symbol for "Sterilized with ethylene oxide"


Symbol for "non-reuse"

Symbol for "Do not re-sterilize"


Symbol for "Do not use if packaging is damaged"


Symbol for "Expiry Date"


Symbol for "keep dry"


Symbol for "protect from sunlight"


Symbol for "Attention"

Symbol for "Do not use this device in MR fields"