

INFORMATION FOR

PATIENT

(Please pass it to the patient)

Niti-S Enteral Colonic Stent

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1. Model Name:

- Niti-S Enteral Colonic Uncovered Stent [S-Type]
- Niti-S Enteral Colonic Uncovered Stent [D-Type]
- Niti-S Enteral Colonic Covered Stent [Full Covered-Type]
- Niti-S Enteral Colonic Covered Stent [Both Bare-Type]
- Niti-S Enteral Colonic Covered Stent [End Bare-Type]
- ComVi Enteral Colonic Stent [Both Bare-Type]

2. What material is stent made of?:

The stent is made up of different materials, like:

- Nitinol
- Platinum/Iridium
- Stainless Steel
- Silicone (only in covered stents)
- Polytetrafluoroethylene - PTFE (only in covered stents)
- Nylon (only in covered stents)
- Polyester (only in covered stents)

Nitinol is a mix of nickel and titanium. Nickel might be released from the stent. Nickel is known to have some health risks. It is suspected to human carcinogen. And it is known or presumed human reproductive toxicant. But, the amount of nickel from the device released is quite low (6.95 times lower than the safety margin). This means that the stent is safe for adults. Except for nickel, the stent does not contain any other materials in high amounts (> 0.1 % weight by weight).

3. How long will the stent stay in?: The device has been verified to function in the body for up to 1 year. But, how long it really lasts might depend on your specific health situation, so please consult with your doctor.

4. When should I call for help?

If you experience any of the below problems, please contact your doctor:

- Bleeding, pain, fever
- The constant feeling of a lump or something is stuck
- Trouble going to the bathroom
- Frequent loose stool
- Swelling and redness on your belly
- Old symptoms coming back

Please note that these are just some of the symptoms you might have. If you have constant bleeding, clotting issues, feel any burn, have a nickel allergy, or anything else, please go to your hospital right away.

5. What should I do after I received a stent?

- It is important to get routine medical care.
- Please carry your implant card with you at all times. The implant card has important information about your metal stent that healthcare providers might need to know to provide better care. The card is conveniently sized to fit in a wallet.
- In the event of a serious incident related to the device, please report it to your hospital.
- You can also find the latest Information for Patient at: www.taewoongmedical.com