# 1. Introduction

This Technical Data Sheet consists of documentation relating to products, Stent; Niti-S Tracheobronchial Stent which meet the requirements of the Medical Device Directive 93/42/EEC as amended by 2007/47/EC, and which are requested to bear the CE mark to enable them to move freely within the European Community and to be put into service in accordance with their intended purpose. Information in this technical data sheet is extracted from technical file TCF 06-01 (Rev.6).

# 2 Manufacturer

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# 3 EC Representative

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# 4. Product description

Niti-S Tracheobronchial Stent is self-expanding endoprosthesis composed of nickel titanium alloy (nitinol). This stent is used to enlarge tracheobronchial duct for patients suffering from tracheobronchial cancer and benign stricture.

Niti-S Tracheobronchial stent consists of Niti-S Stent, main body, and Introducer system, which help to insert stent. After the operation, Niti-S Trachobronchial Stent remains at the intended part of patients and the Introducer system is taken off.

Since nitinol, self-expanding endoprosthesis, was applied in 1980s, it is widely used all over the world. Taewoong Medical Co., Ltd. utilizes the state of the art technology. And apply the essential requirements of MDD 93/42/EEC as amended by 2007/47/EC and ISO 14630 from the beginning stage of the device design.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Trade name | Type | Shape | Coverage | Covered Material | Introducer  system |
| Niti-S Tracheal  Covered Stent | Flare Type | Single Flare | Full covered | PTFE | 14Fr or more |
| Niti-S Bronchial  Covered Stent | D Type | Straight | Full covered | PTFE | 12Fr and 14Fr |

**Classification:** - **Stent:** Class IIb by Rule 5 of Annex IX, MDD 93/42/EEC as amended by 2007/47/EC

- **Introducer** (Stent Delivery System): Class I by Rule 5 Annex IX, MDD 93/42/EEC

as amended by 2007/47/EC

# 5. Indication

**5.1 Indication for use**

The Niti-S Tracheobronchial Stent is intended for maintaining tracheal or bronchial luminal patency in tracheobronchial strictures caused by intrinsic and/or extrinsic malignant and/or benign stricture.

**5.2 Contraindications**

Niti-S Tracheobronchial Stent is contraindicated for, but is not limited to;

- Placement in polypoid lesions

- Patient with bleeding disorder

- Intra-abdominal abscess/perforation

- Patients with coagulopathy

- Strictures that do not allow passage of a guide wire

- Any use other than those specifically outlined under indications for use

- Removal or repositioning of fully deployed uncovered/bare Stents is contraindicated

- Suspected or impending perforation

- Recapturing a stent during its deployment is contraindicated.

**5.3 Potential Complication**

|  |  |
| --- | --- |
| Procedural Complications | |
| - Bleeding  - Stent misplacement  - Pain  - Death (other than that due to normal disease progression)  - Perforation  - Deployment failure | |
| Post Stent Placement Complications | |
| - Bleedings  - Pain  - Perforation  - Stent migration  - Stent occlusion  - Tumor overgrowth  - Tumor ingrowth  - Death (other than that due to normal disease progression)  - Fever  - Foreign body sensation  - Sepsis  - Infection  - Acute cholecystitis  - Edema  - Pneumothorax | - Halitosis  - Hemoptysis  - Restenosis  - Dyspnea  - Stent fracture  - Hypoxia  - Cough  - Granulation tissue formation  - Stent misshaping  - Tracheoesophageal fistula  - Pneumonia  - Respiratory failure  - Retentions of secretions  - Atelectasis  - Ischemia |

# 6. Photos

**6.1 Stent**

Niti-S Tracheobronchial Stent is intended to be implanted to restore the structure and/or function of the tracheobronchial duct. It is woven of endless Nitinol wire to avoid sharp edges. It has radiopaque markers of Pt/Ir at both ends and/or center to facilitate imaging through X-ray photograph.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Model Name | Type | Shape | Coverage | Covered Material | Photo |
| Niti-S Tracheal  Covered Stent | Flare Type | Single Flare | Full Covered | PTFE |  |
| Niti-S Bronchial  Covered Stent | D Type | Straight | Full Covered | PTFE |  |

**6.2** **Introducer System**

Introducer is a system to deliver and deploy stent at the target position. It consists of Inner catheter, Outer sheath, Hub, Y-connector, Tip and Pusher.

All these components of the introducer are supplied with sterilization in a pack and it is disposable.

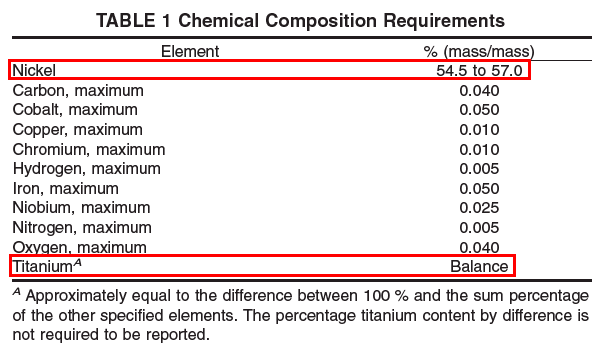
|  |  |
| --- | --- |
| * **Introducer system <14Fr or more >**  |  | | --- | | Tip  1st inner catheter (inside)  2nd inner catheter  Introducer-OTW  Hub  Pusher  Y-Connector  Outer Sheath | |
| * **Introducer system <12Fr.>**   1st inner catheter (inside)  2nd inner catheter (inside)  Tip    Pusher  Y-connector  Outer Sheath  Hub 7. Illustrations**7.1 Stent**  Nti-S Tracheobrochial Stent is woven of endless nitinol wire to avoid sharp edges. It has radiopaque markers of Pt/Ir at both ends and center to facilitate imaging through X-ray photograph.  It is used to enlarge tracheobronchial for patients who are suffering from cancer and benign stricture.   1. **Niti-S Tracheal Covered Stent**  * Flare Type [Full Covered]   1)Pt/I r 2)STS316L  Niti-S Tracheal Covered Stent [Flare Type] is composed of nitinol wire; (Pt/Ir) and (STS 316L tube) markers. It is single-strand Nitinol design engineered to exert constant radial pressure to maintain patency. The stent is produced using the unique sandwich structure. 1): outer D-type straight stent, 2): inner S-Type flare stent 3) between outer and inner: PTFE cover. PTFE covering is designed to help resist tumor ingrowths and occlude tracheal fistula. Radiopaque markers help target the deployed position of the stent. The total length of Niti-S Tracheal Covered stent [Flare Type] is from 30 to 100mm, and the diameters are 16, 18, 20, 22, 24mm.  nds to palliate migration. Radiopaque markers help target the deployed position of the stent. The total length of Niti-S Bronchial Uncovered Stent is from 30 to 60mm, and the diameters are 10, 12, 14,16mm.   1. **Niti-S Bronchial Covered Stent**  * D Type [Full Covered]   1)Pt/I r 2)STS316L  Niti-S Bronchial Covered Stent [D Type] is composed of nitinol wire; (Pt/Ir) and (STS 316L tube) markers. It is single-strand Nitinol design engineered to exert constant radial pressure to maintain patency.  The stent is produced using the unique sandwich structure. . 1): outer D-type straight stent, 2): inner S-Type flare stent 3) between outer and inner: PTFE cover. It has a straight body with a flare at both ends to palliate migration. Radiopaque markers help target the deployed position of the stent. The total length of Niti-S Tracheal Covered Stent is from 30 to 60mm, and the diameters are 10, 12 14 and 16mm. **7.2 Introducer**   Introducer is a system to deliver and deploy stent at the target position. It consists of Inner catheters, Outer sheath, Hub, Connector & Tip. All these components are disposable.   1. **14Fr or more**  * Introducer      * Introducer & Stent      * Part Name  1. Hub: Handle of inner catheter. 2. 2nd Inner Catheter: It is a support to keep stent at the end of first inner catheter. 3. Y-connector: Handle of outer sheath to pull and push. 4. Outer sheath: Tube for holding and delivering stent. First and second inner catheter is inside outer sheath. 5. Yellow Marker: It shows the rear position of introducer during the operation through endoscope. 6. Proximal X-ray marker: It shows the rear position of introducer during the operation through X-ray. 7. 1st inner catheter: It’s a PEEK tube, the most inner part of the introducer used as a passage for a guide wire, connected from hub to tip. 8. Center X-ray Marker: It shows between proximal x-ray marker and distal x-ray marker position of introducer during the operation through X-ray. 9. Distal X-ray marker: It shows the front position of introducer during the operation through X-ray. 10. Tip: Front part of introducer. 11. Stent: Stent 12. Holder: it’s an extruded tube to holding the stent in outer sheath and attached on the first inner catheter. 13. Side hole: Saline injection hole 14. Hole: Central lumen for guide wire passage. 15. **12Fr**  * Introducer      * Introducer & Stent     \* A: Inner sheath, B: Outer sheath   * Part Name  1. Hub: Handle of inner catheter. 2. Pusher: Stainless steel tube for support when outer sheath is pulled. 3. Y-connector: handle of outer sheath to pull and push. 4. Outer sheath: Braided tube for holding and delivering stent. First and second inner catheter   is inside outer sheath.   1. 2nd inner catheter: It is a support to keep stent at the end of first inner catheter. 2. Yellow Marker: It shows the rear position of introducer during the operation through endoscope. 3. Proximal X-ray marker: It shows the rear position of introducer during the operation through X-ray. 4. 1st inner catheter: it’s a tube and introducer through endoscope. 5. Center X-ray marker: It shows between proximal x-ray marker and distal x-ray marker position of   introducer during the operation through X-ray.   1. Distal X-ray marker: It shows the front position of introducer during the operation through X-ray 2. Tip: Front part of introducer. 3. Stent 4. Holder: it’s an extruded tube to holding the stent in outer sheath and attached on the first Inner catheter  8. Product parameters |
| |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Model Name: Niti-S Tracheobronchial CoveredStent [Full Covered-Type]** | | | | | | | | | | | | | | |  | | | | | Introducer type: Endoscopic  Shape: Single Flare Coverage: Full Covered / PTFE | | | | | | | | | | Art No. | UDI-DI | Stent | | | | | | | | Cover | Introducer System | | | | Body | | Head | | | | | Total Length (mm) | PTFE | Diameter  (mm) | Usable  Length  (cm) | Total  Length  (cm) | | Diameter  (mm) | Length (mm) | Diameter  (mm) | | | Length  (cm) | | Length (mm) | | L | | R | L | R | | **TR1603FP** | 08809233108192 | 16±0.8 | 23±1.2 | N/A | | 24±1.2 | N/A | 7±0.35 | 30±1.5 | 30±1.5 | 5.3±0.53  (16Fr) | 60±6.0 | 83±8.3 | | **TR1604FP** | 08809233108208 | 33±1.7 | 40±2.0 | 40±2.0 | 85±8.5 | | **TR1605FP** | 08809233108215 | 43±2.2 | 50±2.5 | 50±2.5 | 86±8.6 | | **TR1606FP** | 08809233108222 | 53±2.7 | 60±3.0 | 60±3.0 | 87±8.7 | | **TR1607FP** | 08809233108239 | 63±3.2 | 70±3.5 | 70±3.5 | 88±8.8 | | **TR1608FP** | 08809233108246 | 73±3.7 | 80±4.0 | 80±4.0 | 89±8.9 | | **TR1609FP** | 08809233108253 | 83±4.2 | 90±4.5 | 90±4.5 | 90±9.0 | | **TR1610FP** | 08809233108260 | 93±4.7 | 100±5.0 | 100±5.0 | 91±9.1 | | **TR1803FP** | 08809234334262 | 18±0.9 | 23±1.2 | N/A | | 26±1.3 | N/A | 7±0.35 | 30±1.5 | 30±1.5 | 6.0±0.6  (18Fr) | 60±6.0 | 84±8.4 | | **TR1804FP** | 08809234334279 | 33±1.7 | 40±2.0 | 40±2.0 | 85±8.5 | | **TR1805FP** | 08809234334286 | 43±2.2 | 50±2.5 | 50±2.5 | 86±8.6 | | **TR1806FP** | 08809234334293 | 53±2.7 | 60±3.0 | 60±3.0 | 87±8.7 | | **TR1807FP** | 08809234334309 | 63±3.2 | 70±3.5 | 70±3.5 | 88±8.8 | | **TR1808FP** | 08809233108277 | 73±3.7 | 80±4.0 | 80±4.0 | 89±8.9 | | **TR1809FP** | 08809234334316 | 83±4.2 | 90±4.5 | 90±4.5 | 90±9.0 | | **TR1810FP** | 08809234334323 | 93±4.7 | 100±5.0 | 100±5.0 | 91±9.1 | | **TR2003FP** | 08809233108284 | 20±1.0 | 23±1.2 | N/A | | 28±1.4 | N/A | 7±0.35 | 30±1.5 | 30±1.5 | 6.0±0.6  (18Fr) | 60±6.0 | 83±8.3 | | **TR2004FP** | 08809233108291 | 33±1.7 | 40±2.0 | 40±2.0 | 84±8.4 | | **TR2005FP** | 08809233108307 | 43±2.2 | 50±2.5 | 50±2.5 | 85±8.5 | | **TR2006FP** | 08809233108314 | 53±2.7 | 60±3.0 | 60±3.0 | 86±8.6 | | **TR2007FP** | 08809233108321 | 63±3.2 | 70±3.5 | 70±3.5 | 87±8.7 | | **TR2008FP** | 08809233108338 | 73±3.7 | 80±4.0 | 80±4.0 | 88±8.8 | | **TR2009FP** | 08809233108345 | 83±4.2 | 90±4.5 | 90±4.5 | 89±8.9 | | **TR2010FP** | 08809233108352 | 93±4.7 | 100±5.0 | 100±5.0 | 90±9.0 | | **TR2203FP** | 08809234334880 | 22±1.1 | 23±1.2 | N/A | | 30±1.5 | N/A | 7±0.35 | 30±1.5 | 30±1.5 | 6.0±0.6  (18Fr) | 60±6.0 | 83±8.3 | | **TR2204FP** | 08809234334972 | 33±1.7 | 40±2.0 | 40±2.0 | 85±8.5 | | **TR2205FP** | 08809234334842 | 43±2.2 | 50±2.5 | 50±2.5 | 86±8.6 | | **TR2206FP** | 08809234334163 | 53±2.7 | 60±3.0 | 60±3.0 | 87±8.7 | | **TR2207FP** | 08809234334859 | 63±3.2 | 70±3.5 | 70±3.5 | 88±8.8 | | **TR2208FP** | 08809293833966 | 73±3.7 | 80±4.0 | 80±4.0 | 89±8.9 | | **TR2209FP** | 08809233108857 | 83±4.2 | 90±4.5 | 90±4.5 | 90±9.0 | | **TR2210FP** | 08809233108864 | 93±4.7 | 100±5.0 | 100±5.0 | 91±9.1 | | **TR2403FP** | 08809234334866 | 24±1.2 | 23±1.2 | N/A | | 32±1.6 | N/A | 7±0.35 | 30±1.5 | 30±1.5 | 6.0±0.6  (18Fr) | 60±6.0 | 83±8.3 | | **TR2404FP** | 08809234334873 | 33±1.7 | 40±2.0 | 40±2.0 | 84±8.4 | | **TR2405FP** | 08809234334897 | 43±2.2 | 50±2.5 | 50±2.5 | 85±8.5 | | **TR2406FP** | 08809234334903 | 53±2.7 | 60±3.0 | 60±3.0 | 86±8.6 | | **TR2407FP** | 08809234334910 | 63±3.2 | 70±3.5 | 70±3.5 | 87±8.7 | | **TR2408FP** | 08809233108871 | 73±3.7 | 80±4.0 | 80±4.0 | 88±8.8 | | **TR2409FP** | 08809233108888 | 83±4.2 | 90±4.5 | 90±4.5 | 89±8.9 | | **TR2410FP** | 08809233108895 | 93±4.7 | 100±5.0 | 100±5.0 | 90±9.0 |   **Ex) TR1603FP: TR**:Tracheal Stent, **16**:Diameter(mm), **03**:Length(cm), **F**:Full Covered, **P**:Single Flare  **Note**: PTFE Covered and Double Layer   |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Model Name: Niti-S Tracheobronchial CoveredStent [Full Covered-Type]** | | | | | | | | | | | | | | |  | | | | | Introducer type: Endoscopic  Shape: Straight Coverage: Full Covered / PFTE | | | | | | | | | | Art No. | UDI-DI | Stent | | | | | | | | Cover | Introducer System | | | | Body | | Head | | | | | Total Length (mm) | None | Diameter  (mm) | Usable  Length  (cm) | Total  Length  (cm) | | Diameter  (mm) | Length (mm) | Diameter(mm) | | | Length(mm)  (cm) | | Length (mm) | | L | | R | L | R | | **BR1003F** | 08809233108529 | 10±0.5 | 30±1.5 | N/A | | N/A | N/A | N/A | 30±1.5 | 30±1.5 | 4.0±0.4  (12Fr) | 60±6.0 | 80±8.0 | | **BR1004F** | 08809233108536 | 40±2.0 | 40±2.0 | 40±2.0 | 81±8.1 | | **BR1005F** | 08809233108543 | 50±2.5 | 50±2.5 | 50±2.5 | 83±8.3 | | **BR1006F** | 08809233108550 | 60±3.0 | 60±3.0 | 60±3.0 | 84±8.4 | | **BR1203F** | 08809233108574 | 12±0.6 | 30±1.5 | N/A | | N/A | N/A | N/A | 30±1.5 | 30±1.5 | 4.0±0.4  (12Fr) | 60±6.0 | 80±8.0 | | **BR1204F** | 08809233108581 | 40±2.0 | 40±2.0 | 40±2.0 | 81±8.1 | | **BR1205F** | 08809233108598 | 50±2.5 | 50±2.5 | 50±2.5 | 83±8.3 | | **BR1206F** | 08809233108604 | 60±3.0 | 60±3.0 | 60±3.0 | 84±8.4 | | **BR1403F** | 08809233108628 | 14±0.7 | 30±1.5 | N/A | | N/A | N/A | N/A | 30±1.5 | 30±1.5 | 4.0±0.4  (12Fr) | 60±6.0 | 80±8.0 | | **BR1404F** | 08809233108635 | 40±2.0 | 40±2.0 | 40±2.0 | 81±8.1 | | **BR1405F** | 08809233108642 | 50±2.5 | 50±2.5 | 50±2.5 | 83±8.3 | | **BR1406F** | 08809233108659 | 60±3.0 | 60±3.0 | 60±3.0 | 84±8.4 | | **BR1603F** | 08809234333982 | 16±0.8 | 30±1.5 | N/A | | N/A | N/A | N/A | 30±1.5 | 30±1.5 | 4.7±0.47  (14Fr) | 60±6.0 | 80±8.0 | | **BR1604F** | 08809234333999 | 40±2.0 | 40±2.0 | 40±2.0 | 81±8.1 | | **BR1605F** | 08809234334002 | 50±2.5 | 50±2.5 | 50±2.5 | 83±8.3 | | **BR1606F** | 08809293834062 | 60±3.0 | 60±3.0 | 60±3.0 | 84±8.4 |   **Ex) BR1003F: BR**: Bronchial Stent, **10**:Diameter(mm), **03**:Length(cm), **F**:Full Covered;  **Note**: PTFE Covered and Double Layer |

# 9. Specs of Raw materials

**9.1 Stent**

|  |  |  |  |
| --- | --- | --- | --- |
| **Component** | **Duration**  **of contact** | **Chemical Composition (%)** | **CAS #** |
| Nitinol1  Wire | Over  30 days | Nickel (54.5~57),  Titanium (Balance),  Others | 7440-02-0  7440-32-6  - |
| Nickel (55.8),  Titanium (Balance),  Oxygen (~0.05)  Carbon (~0.02) | 7440-02-0  7440-32-6  7782-44-7  7440-44-0 |
| X-ray  Marker | Pt (60~99.94) / Ir (0.1~30) | 7440-06-4/7439-88-5 |
| Stainless Steel (STS316L)  - Iron (Balance)  - Chromium (18.1~18.7)  - Nickel (8.1~8.5) | 7439-89-6  7440-47-3  7440-02-0 |
| PTFE | Polytetrafluoroethylene (PTFE) | 9002-84-0 |
| Suture 2) | Nylon  Adipic acid –  hexamethylenediamine resin (>99)  Hematine HCK Dye (~1.0) | 32131-17-2  475-25-2 |
| Removal  (or repositioning) String | Polyester (Green)  Polyethylene terephthalate (> 98.0)  D&C No. 6 Green (~0.75)  Nu-Sil MED-2174 Elastomer (1~2) | 25038-59-9  128-80-3  Mixture |

1) Taewoong Medical is manufacturing stents using either Nitinol wire from NDC or Furukawa. Since Nitinol wires meet the requirements of “ASTM F2063-18: Standard specification for Wrought Nickel-Titanium Shape memory Alloys for Medical Devices and Surgical Implants” as below table (Nickel: 54.5 to 57.0% mass/mass, Titanium: Balance), any test performed on either Nitinol also applies to the other one.



2) Suture (nylon) is used for the connection between PTFE and nitinol wires.

**9.2 Introducer System**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Component | Duration  of Contact | Chemical  Composition (%) | CAS # | Introducer Type | |
| 14Fr  or more | 12Fr |
| Hub  & Y-Connector | N/A | ABS  - 2-Propenenitrile polymer with  1,3-butadiene and  ethenylbenzene (95~100)  - Confidential (1~10) | 9003-56-9  - | O | O |
| Pusher | Stainless Steel 304  - Iron (Balance)  - Chromium (18.1~18.7)  - Nickel (8.1~8.5) | 7439-89-6  7440-47-3  7440-02-0 | O | O |
| Outer  Sheath | Temporary invasive/  less than 30min | Polytetrafuoroethylene  (PTFE) | 9002-84-0 | O | O |
| 2nd Inner  Catheter | Poly[imino(1,6-dioxo-1,6-hexanediyl)  imino-1,6-hexanediyl]  (99-100) | 32131-17-2 | X | O |
| 1-Propene, polymer with  ethene (95~100)  Confidential (~1) | 9010-79-1  - | O | X |
| Pigment (0~60)  Synthetic resin (10~40)  Aromatic Hydrocarbon (20~60)  Trimethylbenzene (1~10) | -  -  64742-94-5  25551-13-7 | O | X |
| Yellow  Marker | Poly[imino(1,6-dioxo-1,6-hexanediyl)  imino-1, 6-hexanediyl] (99-100) | 32131-17-2 | O | O |
| Titanium dioxide (90~99)  Silicon dioxide, amorphous (<10)  Aluminum hydroxide (<10) | 13463-67-7  7631-86-9  21645-51-2 | O | O |
| Carbon Black, amorphous (>99) | 1333-86-4 | O | O |
| Disobutyl 3,9-  peryenedicarboxylate (100) | 2744-50-5 | O | O |
| 6-(Cyclohexylamino)-3-N-  methylanthrapyridone (100) | 21295-57-8 | O | O |
| Proximal/  Center/Distal  X-ray Marker | Tungsten (>99.95) | 7440-33-7 | O | O |
| Holder | PEBAX | 77402-38-1 | O | X |
| Polyolefin tube | - | X | O |
| 1st Inner  Catheter | Polyetheretherketone(PEEK) | 31694-16-3 | O | O |
| Tip | PEBAX | 77402-38-1 | O | O |

Note: No Animal Substances are used in the manufacture of these devices and that no medicinal products are used in the manufacture of these devices.

# 10. Performance Data

**10.1 Biocompatibility Testing**

* **Categorization of medical devices [ISO 10993-1:2018, Chapter 5]**

|  |  |  |
| --- | --- | --- |
| **ISO 10993-1:2018, Chapter 5** | **Stent** | **Introducer** |
| 5.2 Categorization by nature of body contact | Implant medical devices  (Tissue) | Surface-contacting medical devices  (Mucosal membranes) |
| 5.3 Categorization by duration of contact | Long-term exposure (C) – medical devices whose cumulative sum of single, multiple or repeated contact time **exceeds 30 d.** | Limited exposure (A) – medical devices whose cumulative sum of single, multiple or repeated duration of contact is **up to 24 h.** |

* **Test results (Stent)**

| Test sample | Test item | Method | Result | P / F |
| --- | --- | --- | --- | --- |
| PTFE COVERED STENT | Cytotoxicity | ISO10993-5 | Reactivity grade  - Test group : 0  - reagent control : 0  - negative control : 0  - positive control : 4 | Pass |
| Sensitization | ISO10993-10 | 1. None  2. Normal body weight increase  3. Skin reaction grade : 0 | Pass |
| Intracutaneous reactivity | ISO10993-10 | 1. None  2. Normal body weight increase  3. Mean score difference between the test & control solution was 1.0 or less | Pass |
| Pyrogenicity | ISO10993-11 | No animal showed body temperature increase of 0.5 ℃ or above | Pass |
| Acute Systemic toxicity | ISO10993-11 | 1. No abnormal signs  2. Normal body weight increase | Pass |
| Subchronic toxicity | ISO 10993-11 | No statistical difference was observed | Pass |
| Genotoxocity | ISO10993-3 | No increase | Pass |
| ISO10993-3 | Less than 5 % increase | Pass |
| Haemocompatibility | ISO10993-4 | Non-Hemolytic | Pass |
| IMPLANTATION | Nitinol | ISO10993-6 | 1. No abnormal signs and dead  2. Normal body weight increase | Pass |
| Pt/Ir | Pass |
| SUS | Pass |
| PTFE | Pass |
| Nylon | Pass |
| Polyester | Pass |

* **Test results (Introducer System)**

| Test sample | Test item | Method | Result | P / F |
| --- | --- | --- | --- | --- |
| 12Fr | Cytotoxicity | ISO10993-5 | Reactivity grade  - Test group : 0  - reagent control : 0  - negative control : 0  - positive control : 4 | Pass |
| Sensitization | ISO10993-10 | 1. None  2. Normal body weight increase  3. Skin reaction grade : 0 | Pass |
| Intracutaneous reactivity | ISO10993-10 | 1. None  2. Normal body weight increase  3. Mean score difference between the test & control solution was 1.0 or less | Pass |
| Pyrogenicity | ISO10993-11 | No animal showed body temperature increase of 0.5 ℃ or above | Pass |
| Acute Systemic toxicity | ISO10993-11 | 1. No abnormal signs  2. Normal body weight increase | Pass |
| 14 Fr or more | Cytotoxicity | ISO10993-5 | Reactivity grade  - Test group : 0  - reagent control : 0  - negative control : 0  - positive control : 4 | Pass |
| Sensitization | ISO10993-10 | 1. None  2. Normal body weight increase  3. Skin reaction grade : 0 | Pass |
| Intracutaneous reactivity | ISO10993-10 | 1. None  2. Normal body weight increase  3. Mean score difference between the test & control solution was 1.0 or less | Pass |
| Pyrogenicity | ISO10993-11 | No animal showed body temperature increase of 0.5 ℃ or above | Pass |
| Acute Systemic toxicity | ISO10993-11 | 1. No abnormal signs  2. Normal body weight increase | Pass |

**10.2 Bench Testing**

Bench Testing Unit tests of the Niti-S Tracheobronchial Stent included External shape testing, Dimensional

testing, Deployment testing, Deployment force testing, Expansion force testing, Compression force testing,

Tensile strength testing, Removal string tensile strength testing, Compatibility with other accessories and

fatigue test. All tests passed the set acceptance criteria.

**10.3 Usability Evaluation**

The Niti-S Tracheobronchial Stent are loaded in 2 different types of introducers: 12Fr or less and 14Fr or more

of the OTW(Over The Wire) introducer. Taewoong Medical has performed usability for both introducers. Both

Formative and Summative usability was performed in accordance with IEC 62366-1: 2015 by more than 40

persons.

Formative evaluation was performed to identify potential use errors and the user interface components of the

stent delivery system, and to identify unexpected use error and collect opinions on user interface in order to

analyze the root-cause of the related use error that could result in any use-related hazards.

Summative evaluation was performed to demonstrate that the intended user can safely perform the tasks given

in the use scenarios of the Niti-S stent delivery system without any use error. This evaluation is also to

implement usability validation in the final stage of product development process for the quality improvement

and continuous enhancement of the requested device.

Based on the Formative and Summative evaluation, it is concluded that there were no risk factors found at the

Niti-S stent delivery system, and the intended users can safely perform the tasks under the hazard-related use

scenarios of stent delivery system without committing use errors.

**10.4 MRI compatibility**

Taewoong has conducted MR Compatibility Testing in accordance with the FDA guidance document “Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment (December 11, 2014)”

**► Magnetic field interactions**

[ASTM F 2052-15 Standard test method for measurement of magnetically induced displacement force

on medical devices in the magnetic resonance environment]

[ASTM F2213-06Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment]

- Testing for magnetic field interactions involved evaluations of translational attraction and torque for the Stent using a 3-Tesla MR system.

**► MRI-related heating**

[ASTM F2182-11a Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging]

- MRI-related heating 1.5-Tesla / 64-MHz

- MRI-related heating 3-Tesla / 128-MHz

**► Artifacts at 3-Tesla**

[ASTM F2119-13, Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants]

# 11. Sterility and Shelf-life

**11.1 Sterilization**

Niti-S Tracheobronchial Stent is supplied with sterilization.

We sterilize Niti-S Tracheobronchial Stent with Ethylene Oxide gas. Ethylene Oxide gas is performed with the

cycle validated on the report SVR-03 in accordance with ISO11135-1: Sterilization of medical devices-

Validation and routine control of sterilization by E.O. gas by a subcontractor certified by SGS UK Ltd.

Certification.

The sterilizing cycle has been validated to ensure our products to be sterilized to an S.A.L. of at least 10-6 by

EN556 by the method of over-kill. These products have been sterilized using this method since first

manufacturing with no sterility failures.

EO and ethylene chlorohydrins (ECH) residuals were measured to ensure that they were within the specified

limits of ISO 10993-7:2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization

residuals. The device was found to be non-pyrogenic after Limulus Amebocye Lysate (LAL) testing.

**11.2 Shelf Life**

The shelf life of Niti-S Tracheobronchial Stent is 3 years. The shelf life testing included package integrity

testing and functional testing of devices aged using accelerated aging to simulate 3-year. The accelerated aging

calculation was based on the Von’t Hoff’s Q10 theory. The functional testing was performed using the same

protocols as the functional testing discussed in the bench testing section, with the same acceptance criteria. This

testing included External shape testing, Dimensional, testing, Deployment testing, Deployment force testing,

Expansion force testing, Compression force testing, Tensile strength testing, Removal string tensile strength

and testing. The functional testing demonstrated that the aged stent performed equivalently to the non-aged

stent. The packaging testing demonstrated package integrity and maintenance of the sterile barrier in the aged

devices

# 12. Clinical Evaluation

This evaluation is based on the assessment conducted and documented in report CER 06-01, in accordance with

1) MDD 93/42/EEC as amended by 2007/47/EC - Annex X

2) NB-MED 2.7/Rec1 Guidance on clinical

3) NB-MED 2.7/Rec3 Evaluation of clinical data

4) MEDDEV 2.7.1 (Rev.4) Clinical Evaluation

5) MEDDEV 2.12.2 (Rev.2) Post Market Clinical Follow-up Studies

Based on the above evaluations it is considered that we need not perform clinical investigation and the safety and performance of Niti-S Tracheobronchial Stent is verified.