

# **DILATION BALLOONS**

# SIMPLY EXPAND RELIABLY AND EFFECTIVELY

The dilation balloons from MICRO-TECH stand for maximum quality. MICRO-TECH produces all the dilation balloons itself – using state-of-the-art European and American production technology. Two x-ray markings indicate the exact working length of the balloon, thereby ensuring its

precise positioning. Under application of pressure, the balloon is rapidly filled to acquire its predefined expansion width. Furthermore, the high-pressure design ensures the balloon retains its shape over the entire working length, thereby allowing optimum dilation success.

# SPECIFIC CHARACTERISTICS

- Dimensionally stable high pressure design
- 2 X-ray markers on opposite ends to indicate the exact working length of the balloon
- Separate guide wire and insufflation lumens
- Conical shaped catheter tip
- Rapid expansion
- Constant dilation over the entire length
- Guide-wire compatible up to 0.035 inches







Conical tip

#### SUCCESSFUL IN PRACTICAL USE

Stenoses are effectively dilated using the MICRO-TECH dilation balloons. The balloon dilates the stenosis safely and gently and prepares the area to be treated in an optimum manner. The uniform distribution of pressure over the entire working length of the balloon and the outstanding dimensional stability during dilation guarantee excellent therapeutic success over the entire length of the stenosis.





Endoscopic control during dilation therapy

#### **SPECIFICATIONS**

| REF                | Balloon Ø mm | Balloon length mm | Catheter Ø Fr | Catheter length mm | Channel Ø mm | Application |
|--------------------|--------------|-------------------|---------------|--------------------|--------------|-------------|
| ACHALASIE-BALLOON  | NS           |                   |               |                    |              |             |
| BDC-26/80-7/10     | 26           | 80                | 7             | 1000               | _            | Achalasie   |
| BDC-30/80-7/10     | 30           | 80                | 7             | 1000               | _            | Achalasie   |
| BDC-34/80-7/10     | 34           | 80                | 7             | 1000               | -            | Achalasie   |
| FIXED WIRE BALLOON | IS           |                   |               |                    |              |             |
| FWB-06/80-6/18-M   | 6-7-8        | 80                | 6             | 1800               | 2.8          | Oesophagus  |
| FWB-08/80-6/18-M   | 8-9-10       | 80                | 6             | 1800               | 2.8          | Oesophagus  |
| FWB-10/80-6/18-M   | 10-11-12     | 80                | 6             | 1800               | 2.8          | Oesophagus  |
| FWB-12/80-6/18-M   | 12-13.5-15   | 80                | 6             | 1800               | 2.8          | Oesophagus  |
| FWB-15/80-6/18-M   | 15-16.5-18   | 80                | 6             | 1800               | 2.8          | Oesophagus  |
| FWB-18/80-6/18-M   | 18-19-20     | 80                | 6             | 1800               | 2.8          | Oesophagus  |

Packaging unit: 1 piece / suitable for guide wires with 0.035"



# **NETS**

# SAFELY REMOVE FOREIGN BODIES AND POLYPS

The MT net has been developed for the removal of polyps and foreign bodies and enables the reliable recovery of tissue samples. The net itself consists of a reinforced thread material, which offers additional safety during recovery. Thanks to its unique dimensional stability and large opening, it facilitates work over several passes

## **SPECIFIC CHARACTERISTICS**

- Large net
- High quality manufacture
- Comfortable 3-ring handle
- Easy and precise opening



Shape stable MT net

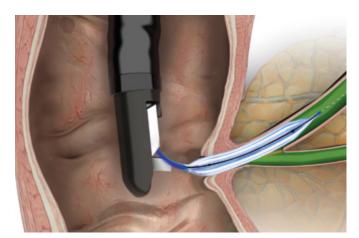
| REF           | Ø net mm | Snare | Working length mm | Ø working channel mm |
|---------------|----------|-------|-------------------|----------------------|
| RETRIEVAL NET |          |       |                   |                      |
| NT-E-30/23-P  | 30       | Oval  | 2300              | 2.8                  |
| NT-E-30/16-P  | 30       | Oval  | 1600              | 2.8                  |

Packaging unit: 10 pieces

#### SINGLE-USE INFLATION-INSTRUMENT

Sturdy construction and an ergonomic handle for easy control. With quick-lock mechanism for one-handed deflation, even under full pressure. The clear cylinder and the easy to read scale allow for a close look at the content and the amount. The exact gauge guarantees reliable pressure measurement.

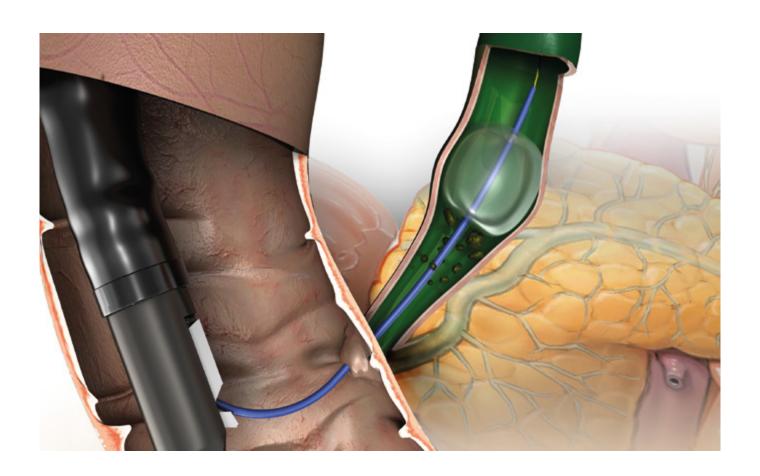




# SPECIFICATIONS

| REF                            | Content ml air | /liquid Ma                                | ax. pressure ATM  |               | Feature            |
|--------------------------------|----------------|---|-------------------|---------------|--------------------|
| SINGLE-USE INFLATION-INSTRUMEN | NT             |   |                   |               |                    |
| BID-15-60-01                   | 60             |   | 15                | 3-wa          | ay-stopcock        |
| REF                            | Balloon Ø mm   | Balloon 3-stagedilation<br>pressure (atm) | Balloon length mm | Catheter Ø Fr | Catheter length mm |
| MULTI-STAGE DILATION BALLOONS  |                |   |                   |               |                    |
| MBD-AS-BB-2                    | 6/7/8          | 3/6/10                                    | 30                | 7             | 2300               |
| MBD-AM-BA-2                    | 6/7/8          | 3/6/10                                    | 55                | 7             | 1800               |
| MBD-AM-BB-2                    | 6/7/8          | 3/6/10                                    | 55                | 7             | 2300               |
| MBD-AL-BA-2                    | 6/7/8          | 3/6/10                                    | 80                | 7             | 1800               |
| MBD-BS-BB-2                    | 8/9/10         | 3/5.5/9                                   | 30                | 7             | 2300               |
| MBD-BM-BA-2                    | 8/9/10         | 3/5.5/9                                   | 55                | 7             | 1800               |
| MBD-BM-BB-2                    | 8/9/10         | 3/5.5/9                                   | 55                | 7             | 2300               |
| MBD-BL-BA-2                    | 8/9/10         | 3/5.5/9                                   | 80                | 7             | 1800               |
| MBD-CS-BB-2                    | 10 / 11 / 12   | 3/5/8                                     | 30                | 7             | 2300               |
| MBD-CM-BA-2                    | 10 / 11 / 12   | 3/5/8                                     | 55                | 7             | 1800               |
| MBD-CM-BB-2                    | 10 / 11 / 12   | 3/5/8                                     | 55                | 7             | 2300               |
| MBD-CL-BA-2                    | 10 / 11 / 12   | 3/5/8                                     | 80                | 7             | 1800               |
| MBD-DS-BB-2                    | 12 / 13.5 / 15 | 3 / 4.5 / 8                               | 30                | 7             | 2300               |
| MBD-DM-BA-2                    | 12 / 13.5 / 15 | 3 / 4.5 / 8                               | 55                | 7             | 1800               |
| MBD-DM-BB-2                    | 12 / 13.5 / 15 | 3 / 4.5 / 8                               | 55                | 7             | 2300               |
| MBD-DL-BA-2                    | 12 / 13.5 / 15 | 3 / 4.5 / 8                               | 80                | 7             | 1800               |
| MBD-EM-BA-2                    | 15 / 16.5 / 18 | 3 / 4.5 / 7                               | 55                | 7             | 1800               |
| MBD-EM-BB-2                    | 15 / 16.5 / 18 | 3 / 4.5 / 7                               | 55                | 7             | 2300               |
| MBD-EL-BA-2                    | 15 / 16.5 / 18 | 3 / 4.5 / 7                               | 80                | 7             | 1800               |
| MBD-FM-BA-2                    | 18 / 19 / 20   | 3 / 4.5 / 6                               | 55                | 7             | 1800               |
| MBD-FM-BB-2                    | 18 / 19 / 20   | 3 / 4.5 / 6                               | 55                | 7             | 2300               |
| MBD-FL-BA-2                    | 18 / 19 / 20   | 3 / 4.5 / 6                               | 80                | 7             | 1800               |

Packaging unit: 1 piece / suitable for guide wires with 0.035"



| REF  | Ø inches | Total length<br>mm | Tip length<br>mm | Tip form | Set-up           |              | Covering             |
|--|----------|--------------------|------------------|----------|------------------|--------------|----------------------|
| CLASSIC GUIDE WIRE   |          |                    |                  |          |                  |              |                      |
| 600382-5   | 0.035"   | 4200               | 130              | straight | hydrophilic, rad | diopaque     | extra stiff ≙ 0.035" |
| HYDRO-SLIDE GUIDE WIF  | RE       |                    |                  |          |                  |              |                      |
| MTN-BM-63/45-A-S   | 0.025"   | 4500               | 60               | straight | hydrophilic, rad | diopaque     | extra stiff ≙ 0.035" |
| MTN-BM-63/45-A-J-S   | 0.025"   | 4500               | 60               | J-form   | hydrophilic, rad | diopaque     | extra stiff ≙ 0.035" |
|  |          |                    |                  |          |                  |              |                      |
| REF  |          | Injecti            | on               | Lumen    | Catheter Ø Fr.   | Balloon Ø mm | Working length mm    |
| STONE EXTRACTION BAL   | LOONS    |                    |                  |          |                  |              |                      |
| SRB-T-9/12/15-20   |          | Above (distal to   | the balloon)     | 3        | 7                | 9 / 12 / 15  | 2000                 |
| SRB-T-12/15/18-20  |          | Above (distal to   | the balloon)     | 3        | 7                | 12 / 15 / 18 | 2000                 |
| SRB-T-15/18/21-20  |          | Above (distal to   | the balloon)     | 3        | 7                | 15 / 18 / 21 | 2000                 |
| SRB-T-9/12/15-20-B   |          | Below (proximal t  | to the balloon)  | 3        | 7                | 9 / 12 / 15  | 2000                 |
| SRB-T-12/15/18-20-B  |          | Below (proximal t  | to the balloon)  | 3        | 7                | 12 / 15 / 18 | 2000                 |
| SRB-T-15/18/21-20-B  |          | Below (proximal t  | to the balloon)  | 3        | 7                | 15 / 18 / 21 | 2000                 |
| Personmended guidauring: MTN PM 90/45 A /0.025 straight) and 600259 5 /0.025 straight) |          |                    |                  |          |                  |              |                      |

Recommended guidewires: MTN-BM 89/45-A (0.035 straight) and 600358-5 (0.035 straight)

Packaging unit: 1 piece



# **GUIDE WIRES**

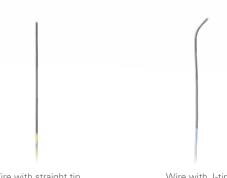
# THE RELIABLE CHOICE FOR ERCP

All guide wires are manufactured out of bending-resistant and torsion-proof Nitinol. Their hydrophilic coated tips, allow the wires to safely find their way even into areas and stenoses which are hard to reach. This is supported by the wire's high rigidity and controllability. Hence the guide

wires are not only meant for sophisticated stent placements, but are also perfectly suited for ERCP. The high radiopacity of the flexible hydrophilic tip facilitates exact stent placement under visual radiological control.

## **SPECIFIC CHARACTERISTICS**

- High level of rigidity and guidability
- Hydrophilic, atraumatic tip
- High level of radiopacity



Wire with straight tip

Wire with J-tip

# **SPIRATRAX**

- Excellent feed force for fast access through stenoses
- High kink resistance for reliable performance
- Simplified handling when instrumenting
- Optimal positionability due to improved stability

Corrugated wire design improves maneuverability

The 0.025-inch hydrophilic tip allows for atraumatic, controlled advancement through the narrowest anatomical structures

The transition to the 0.035-inch shaft ensures optimal guidance and steady support throughout the procedure

### **SPECIFICATIONS**

| REF                    | Ø inches           | Total length<br>mm | Tip length<br>mm | Tip form | Set-Up                  | Feature              |
|------------------------|--------------------|--------------------|------------------|----------|-------------------------|----------------------|
| SPIRATRAX GUIDE WIRES  |                    |                    |                  |          |                         |                      |
| MTN-BM-89/45-A-W       | 0.025"<br>(0.035") | 4500               | 60               | straight | blue-yellow             | corrugated           |
| MTN-BM-89/45-A-J-W     | 0.025"<br>(0.035") | 4500               | 60               | J-form   | blue-yellow             | corrugated           |
| HYDRO-SLIDE GUIDE WIRE | S                  |                    |                  |          |                         |                      |
| MTN-BM-89/45-A         | 0.035"             | 4500               | 60               | straight | hydrophilic, radiopaque | blue-yellow covering |
| MTN-BM-89/45-A-J       | 0.035"             | 4500               | 60               | J-form   | hydrophilic, radiopaque | blue-yellow covering |
| MTN-BM-63/45-A         | 0.025"             | 4500               | 60               | straight | hydrophilic, radiopaque | blue-yellow covering |
| MTN-BM-63/45-A-S       | 0.025"             | 4500               | 60               | straight | hydrophilic, radiopaque | extra stiff ≙ 0.035" |
| MTN-BM-63/45-A-J       | 0.025"             | 4500               | 60               | J-form   | hydrophilic, radiopaque | blue-yellow covering |
| MTN-BM-63/45-A-J-S     | 0.025"             | 4500               | 60               | J-form   | hydrophilic, radiopaque | extra stiff ≙ 0.035" |
| MTN-BM-53/45-A         | 0.021"             | 4500               | 60               | straight | hydrophilic, radiopaque | blue-yellow covering |
| MTN-BM-45/45-A         | 0.018"             | 4500               | 60               | straight | hydrophilic, radiopaque | blue-yellow covering |
| CLASSIC GUIDE WIRES    |                    |                    |                  |          |                         |                      |
| 600382-5               | 0.035"             | 4200               | 130              | straight | hydrophilic, radiopaque | extra stiff ≙ 0.035" |

Packaging unit: SpiraTrax guide wire: 2 pieces, Hydro-Slide guide wire: 2 pieces, classic guide wire: 1 piece



# PLASTIC BILE DUCT STENTS

# MAXIMUM DRAINAGE, MAXIMUM HOLD

MICRO-TECH offers a comprehensive range of plastic stents for short and medium-term drainage in the bile duct. The stents are available in different shapes, lengths and diameters. Thus, the ideal stent is available for each indication. The high-quality PE-/PTFE-material of the stents ensures reliable drainage and adapts optimally

to the anatomy of the patient. Flaps at the ends of the stents also ensure a secure hold with minimal migration. For rapid and safe implantation, the stents are available both individually and on pre-loaded systems. In addition, MICRO-TECH also offers introduction-systems in all relevant sizes.

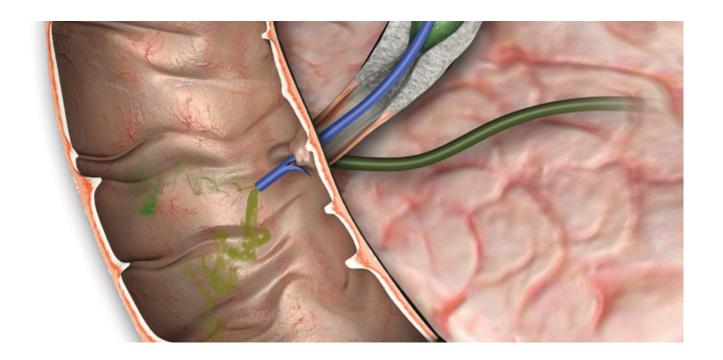
#### **SPECIFIC CHARACTERISTICS**

- Different shapes: straight, curved, angled, pigtail, double-pigtail
- Optimum flow rate
- Ideal adaptation to anatomy
- Safe hold, minimal migration
- Available single-packed or pre-loaded on introduction-system
- High x-ray visibility



Pre-loaded stent

System handle



#### **STENT STRAIGHT**



- Shape: straight
- 2 flaps
- 2 side-holes
- X-ray visible
- Material: PE

#### Diameter bile duct prosthesis

| Working length | 7 Fr.           | 8.5 Fr.         | 10 Fr.          | 11.5 Fr.        |
|----------------|-----------------|-----------------|-----------------|-----------------|
| 5 cm           | BPDS-31114-0705 | BPDS-31114-0805 | BPDS-31114-1005 | BPDS-31114-1105 |
| 6 cm           | BPDS-31114-0706 | BPDS-31114-0806 | BPDS-31114-1006 | BPDS-31114-1106 |
| 7 cm           | BPDS-31114-0707 | BPDS-31114-0807 | BPDS-31114-1007 | BPDS-31114-1107 |
| 8 cm           | BPDS-31114-0708 | BPDS-31114-0808 | BPDS-31114-1008 | BPDS-31114-1108 |
| 9 cm           | BPDS-31114-0709 | BPDS-31114-0809 | BPDS-31114-1009 | BPDS-31114-1109 |
| 10 cm          | BPDS-31114-0710 | BPDS-31114-0810 | BPDS-31114-1010 | BPDS-31114-1110 |
| 11 cm          | BPDS-31114-0711 | BPDS-31114-0811 | BPDS-31114-1011 | BPDS-31114-1111 |
| 12 cm          | BPDS-31114-0712 | BPDS-31114-0812 | BPDS-31114-1012 | BPDS-31114-1112 |
| 13 cm          | BPDS-31114-0713 | BPDS-31114-0813 | BPDS-31114-1013 | BPDS-31114-1113 |
| 14 cm          | BPDS-31114-0714 | BPDS-31114-0814 | BPDS-31114-1014 | BPDS-31114-1114 |
| 15 cm          | BPDS-31114-0715 | BPDS-31114-0815 | BPDS-31114-1015 | BPDS-31114-1115 |

#### **STENT CURVED**



- Shape: 15° curved
- 2 flaps
- 2 side-holes
- X-ray visible
- Material: PE

| VAV. 1 . 1 1   |                 | Diameter bile   | duct prosthesis |                 |
|----------------|-----------------|-----------------|-----------------|-----------------|
| Working length | 7 Fr.           | 8.5 Fr.         | 10 Fr.          | 11.5 Fr.        |
| 5 cm           | BPDS-32114-0705 | BPDS-32114-0805 | BPDS-32114-1005 | BPDS-32114-1105 |
| 6 cm           | BPDS-32114-0706 | BPDS-32114-0806 | BPDS-32114-1006 | BPDS-32114-1106 |
| 7 cm           | BPDS-32114-0707 | BPDS-32114-0807 | BPDS-32114-1007 | BPDS-32114-1107 |
| 8 cm           | BPDS-32114-0708 | BPDS-32114-0808 | BPDS-32114-1008 | BPDS-32114-1108 |
| 9 cm           | BPDS-32114-0709 | BPDS-32114-0809 | BPDS-32114-1009 | BPDS-32114-1109 |
| 10 cm          | BPDS-32114-0710 | BPDS-32114-0810 | BPDS-32114-1010 | BPDS-32114-1110 |
| 11 cm          | BPDS-32114-0711 | BPDS-32114-0811 | BPDS-32114-1011 | BPDS-32114-1111 |
| 12 cm          | BPDS-32114-0712 | BPDS-32114-0812 | BPDS-32114-1012 | BPDS-32114-1112 |
| 13 cm          | BPDS-32114-0713 | BPDS-32114-0813 | BPDS-32114-1013 | BPDS-32114-1113 |
| 14 cm          | BPDS-32114-0714 | BPDS-32114-0814 | BPDS-32114-1014 | BPDS-32114-1114 |
| 15 cm          | BPDS-32114-0715 | BPDS-32114-0815 | BPDS-32114-1015 | BPDS-32114-1115 |

# **SPECIFICATIONS**

#### **STENT LATERAL ANGLED**



- Form: 45° lateral angled
- 2 flaps
- 2 side-holes
- X-ray visible
- Material: PE

| Working length |                 | Diameter bile o | luct prosthesis |                 |
|----------------|-----------------|-----------------|-----------------|-----------------|
| working tength | 7 Fr.           | 8.5 Fr.         | 10 Fr.          | 11.5 Fr.        |
| 5 cm           | BPDS-33114-0705 | BPDS-33114-0805 | BPDS-33114-1005 | BPDS-33114-1105 |
| 6 cm           | BPDS-33114-0706 | BPDS-33114-0806 | BPDS-33114-1006 | BPDS-33114-1106 |
| 7 cm           | BPDS-33114-0707 | BPDS-33114-0807 | BPDS-33114-1007 | BPDS-33114-1107 |
| 8 cm           | BPDS-33114-0708 | BPDS-33114-0808 | BPDS-33114-1008 | BPDS-33114-1108 |
| 9 cm           | BPDS-33114-0709 | BPDS-33114-0809 | BPDS-33114-1009 | BPDS-33114-1109 |
| 10 cm          | BPDS-33114-0710 | BPDS-33114-0810 | BPDS-33114-1010 | BPDS-33114-1110 |
| 11 cm          | BPDS-33114-0711 | BPDS-33114-0811 | BPDS-33114-1011 | BPDS-33114-1111 |
| 12 cm          | BPDS-33114-0712 | BPDS-33114-0812 | BPDS-33114-1012 | BPDS-33114-1112 |
| 13 cm          | BPDS-33114-0713 | BPDS-33114-0813 | BPDS-33114-1013 | BPDS-33114-1113 |
| 14 cm          | BPDS-33114-0714 | BPDS-33114-0814 | BPDS-33114-1014 | BPDS-33114-1114 |
| 15 cm          | BPDS-33114-0715 | BPDS-33114-0815 | BPDS-33114-1015 | BPDS-33114-1115 |

#### **STENT CENTRAL ANGLED**



- Shape: 90° central angled
- 2 flaps
- 2 side-holes
- X-ray visible
- Material: PE

| We also a leaseth |                 | Diameter bile   | duct prosthesis |                 |
|-------------------|-----------------|-----------------|-----------------|-----------------|
| Working length    | 7 Fr.           | 8.5 Fr.         | 10 Fr.          | 11.5 Fr.        |
| 5 cm              | BPDS-34114-0705 | BPDS-34114-0805 | BPDS-34114-1005 | BPDS-34114-1105 |
| 6 cm              | BPDS-34114-0706 | BPDS-34114-0806 | BPDS-34114-1006 | BPDS-34114-1106 |
| 7 cm              | BPDS-34114-0707 | BPDS-34114-0807 | BPDS-34114-1007 | BPDS-34114-1107 |
| 8 cm              | BPDS-34114-0708 | BPDS-34114-0808 | BPDS-34114-1008 | BPDS-34114-1108 |
| 9 cm              | BPDS-34114-0709 | BPDS-34114-0809 | BPDS-34114-1009 | BPDS-34114-1109 |
| 10 cm             | BPDS-34114-0710 | BPDS-34114-0810 | BPDS-34114-1010 | BPDS-34114-1110 |
| 11 cm             | BPDS-34114-0711 | BPDS-34114-0811 | BPDS-34114-1011 | BPDS-34114-1111 |
| 12 cm             | BPDS-34114-0712 | BPDS-34114-0812 | BPDS-34114-1012 | BPDS-34114-1112 |
| 13 cm             | BPDS-34114-0713 | BPDS-34114-0813 | BPDS-34114-1013 | BPDS-34114-1113 |
| 14 cm             | BPDS-34114-0714 | BPDS-34114-0814 | BPDS-34114-1014 | BPDS-34114-1114 |
| 15 cm             | BPDS-34114-0715 | BPDS-34114-0815 | BPDS-34114-1015 | BPDS-34114-1115 |

# **SPECIFICATIONS**

#### **PIGTAIL DOUBLE O-SHAPE**



- Shape: Pigtail O-Shape
- Double
- 4 side-holes
- X-ray visible
- Material: PE

| Working length |                 | Diameter bile duct prosthesis |                 |
|----------------|-----------------|-------------------------------|-----------------|
| working tength | 7 Fr.           | 8.5 Fr.                       | 10 Fr.          |
| 5 cm           | BPDS-31003-0705 | BPDS-31003-0805               | BPDS-31003-1005 |
| 6 cm           | BPDS-31003-0706 | -                             | -               |
| 7 cm           | BPDS-31003-0707 | BPDS-31003-0807               | BPDS-31003-1007 |
| 8 cm           | -               | BPDS-31003-0808               | -               |
| 9 cm           | BPDS-31003-0709 | -                             | BPDS-31003-1009 |
| 10 cm          | BPDS-31003-0710 | -                             | BPDS-31003-1010 |
| 11 cm          | -               | BPDS-31003-08011              | BPDS-31003-1011 |
| 12 cm          | BPDS-31003-0712 | -                             | BPDS-31003-1012 |
| 15 cm          | BPDS-31003-0715 | -                             | -               |

#### **PIGTAIL DISTAL**



- Shape: Pigtail
- Distal
- 2 side-holes
- X-ray visible
- Material: PE

| W 1: 1 d       | Diameter bile duct prosthesis |                 |  |  |  |
|----------------|-------------------------------|-----------------|--|--|--|
| Working length | 8.5 Fr.                       | 10 Fr.          |  |  |  |
| 5 cm           | BPDS-31196-0805               | BPDS-31196-1005 |  |  |  |
| 6 cm           | BPDS-31196-0806               | BPDS-31196-1006 |  |  |  |
| 7 cm           | BPDS-31196-0807               | BPDS-31196-1007 |  |  |  |
| 8 cm           | BPDS-31196-0808               | BPDS-31196-1008 |  |  |  |
| 9 cm           | BPDS-31196-0809               | BPDS-31196-1009 |  |  |  |
| 10 cm          | BPDS-31196-0810               | BPDS-31196-1010 |  |  |  |
| 11 cm          | BPDS-31196-0811               | BPDS-31196-1011 |  |  |  |
| 12 cm          | BPDS-31196-0812               | BPDS-31196-1012 |  |  |  |
| 13 cm          | BPDS-31196-0813               | BPDS-31196-1013 |  |  |  |
| 14 cm          | BPDS-31196-0814               | BPDS-31196-1014 |  |  |  |
| 15 cm          | BPDS-31196-0815               | BPDS-31196-1015 |  |  |  |

## **SPECIFICATIONS**

#### PIGTAIL PROXIMAL



- Shape: Pigtail
- Proximal
- 2 side-holes
- X-ray visible
- Material: PE

| We also also at | Diameter bile duct prosthesis |                 |  |
|-----------------|-------------------------------|-----------------|--|
| Working length  | 8.5 Fr.                       | 10 Fr.          |  |
| 5 cm            | BPDS-31916-0805               | BPDS-31916-1005 |  |
| 6 cm            | BPDS-31916-0806               | BPDS-31916-1006 |  |
| 7 cm            | BPDS-31916-0807               | BPDS-31916-1007 |  |
| 8 cm            | BPDS-31916-0808               | BPDS-31916-1008 |  |
| 9 cm            | BPDS-31916-0809               | BPDS-31916-1009 |  |
| 10 cm           | BPDS-31916-0810               | BPDS-31916-1010 |  |
| 11 cm           | BPDS-31916-0811               | BPDS-31916-1011 |  |
| 12 cm           | BPDS-31916-0812               | BPDS-31916-1012 |  |
| 13 cm           | BPDS-31916-0813               | BPDS-31916-1013 |  |
| 14 cm           | BPDS-31916-0814               | BPDS-31916-1014 |  |
| 15 cm           | BPDS-31916-0815               | BPDS-31916-1015 |  |

# **INTRODUCER-SYSTEMS WITHOUT STENT**

## **SPECIFICATIONS**



- One step introducer-system
- X-ray visible

New: Extended guide catheter

| REF          | Ø catheter | Guide catheter | Introducer length |
|--------------|------------|----------------|-------------------|
| BPDI-0740/22 | 7 Fr.      | 40 cm          | 220 cm            |
| BPDI-0840/22 | 8.5 Fr.    | 40 cm          | 220 cm            |
| BPDI-1040/22 | 10 Fr.     | 40 cm          | 220 cm            |
| BPDI-1140/22 | 11.5 Fr.   | 40 cm          | 220 cm            |

# **INTRODUCER-SYSTEMS WITH PRE-LOADED STENT**



- One step introducer-system
- X-ray visible

## **SPECIFICATIONS**

#### **STENT STRAIGHT**



- Shape: straight
- 2 flaps
- 2 side-holes
- X-ray visible
- Material: PE

| REF                | Ø catheter | Stent working/<br>total length | Introducer length |
|--------------------|------------|--------------------------------|-------------------|
| BPDS-31114-0805/22 | 8.5 Fr.    | 5/7 cm                         | 220 cm            |
| BPDS-31114-0807/22 | 8.5 Fr.    | 7 / 9 cm                       | 220 cm            |
| BPDS-31114-0809/22 | 8.5 Fr.    | 9 / 11 cm                      | 220 cm            |
| BPDS-31114-0811/22 | 8.5 Fr.    | 11 / 13 cm                     | 220 cm            |
| BPDS-31114-1005/22 | 10 Fr.     | 5/7 cm                         | 220 cm            |
| BPDS-31114-1007/22 | 10 Fr.     | 7 / 9 cm                       | 220 cm            |
| BPDS-31114-1009/22 | 10 Fr.     | 9 / 11 cm                      | 220 cm            |
| BPDS-31114-1011/22 | 10 Fr.     | 11 / 13 cm                     | 220 cm            |

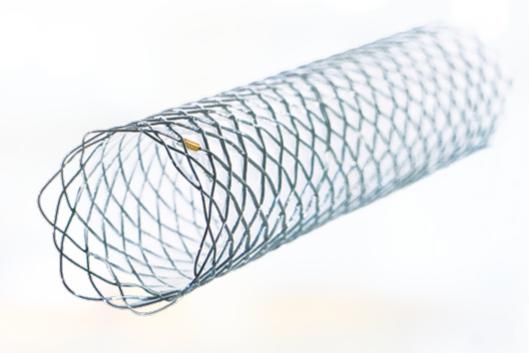
### **SPECIFICATIONS**

#### **STENT CURVED**



- Shape: 15° curved
- 2 flaps
- 2 side-holes
- X-ray visible
- Material: PE

| REF                | Ø catheter | Stent working/<br>total length | Introducer length |
|--------------------|------------|--------------------------------|-------------------|
| BPDS-32114-0805/22 | 8.5 Fr.    | 5 / 7 cm                       | 220 cm            |
| BPDS-32114-0807/22 | 8.5 Fr.    | 7 / 9 cm                       | 220 cm            |
| BPDS-32114-0809/22 | 8.5 Fr.    | 9 / 11 cm                      | 220 cm            |
| BPDS-32114-0811/22 | 8.5 Fr.    | 11 / 13 cm                     | 220 cm            |
| BPDS-32114-1005/22 | 10 Fr.     | 5/7 cm                         | 220 cm            |
| BPDS-32114-1007/22 | 10 Fr.     | 7 / 9 cm                       | 220 cm            |
| BPDS-32114-1009/22 | 10 Fr.     | 9 / 11 cm                      | 220 cm            |
| BPDS-32114-1011/22 | 10 Fr.     | 11 / 13 cm                     | 220 cm            |



# **BILIARY DUCT STENTS**

## **ALWAYS THE IDEAL SOLUTION**

With the biliary stents manufactured by MICRO-TECH you will always make the ideal choice to bridge-graft biliary duct stenoses. The high expansion force of the Nitinol wire mesh accounts for an excellent positional stability. The resistant cover prevents the stent from growing into

the tissue. The product range comprises two stent lines and offers a first-class solution that suits all requirements: the classic line and the platinum line. The comprehensive platinum line is especially distinguished by its extraordinary high radiopacity.

## **SPECIFIC CHARACTERISTICS**

- Self-expanding
- Available for TTS and PTCD
- Classic- and Platinum-Line
- Nitinol wire mesh with atraumatic ends
- Release under visual endoscopic control
- Enormous position stability
- Resistant and elastic cover
- High radiopacity
- Guiding wire passable to a maximum of 0.035 inches



X-ray marking



# **GUIDE WIRES**

# THE RELIABLE CHOICE FOR ERCP

All guide wires are manufactured out of bending-resistant and torsion-proof Nitinol. Their hydrophilic coated tips, allow the wires to safely find their way even into areas and stenoses which are hard to reach. This is supported by the wire's high rigidity and controllability. Hence the guide

wires are not only meant for sophisticated stent placements, but are also perfectly suited for ERCP. The high radiopacity of the flexible hydrophilic tip facilitates exact stent placement under visual radiological control.

## **SPECIFIC CHARACTERISTICS**

- Non-kinking nitinol wire
- High level of rigidity and guidability
- Hydrophilic, atraumatic tip
- Working length: 4500 mm
- High level of radiopacity



Wire with straight tip

#### SUCCESSFUL IN PRACTICAL ROUTINE WORK

Bending resistance and rigidity account for the very good feeding properties of guide wires. In daily applications they convince by their precision, which is primarily guaranteed by the efficient transmission of the rotatory and translatory motion all the way to the tip of the wire, as applied by the surgical assistant. This makes it possible to reach into even anatomically difficult passages with ease. In addition, the tip of each wire can be perfectly seen in the X-ray control image, allowing for optimal stent positioning.







X-ray

#### **DISPENSER FOR EASY OPERATION**

The wire can be easily ejected and retracted by means of this innovative dispenser. Owing to its compact design, the dispenser is handy and easy to operate. Rinsing the wire is also easy and fast when using the dispenser.



Dispenser guide wires

#### **SPECIFICATIONS**

| REF                   | Ø inches | Total length<br>mm | Tip length<br>mm | Tip form | Set-up                  | Covering             |
|-----------------------|----------|--------------------|------------------|----------|-------------------------|----------------------|
| CLASSIC GUIDE WIRE    |          |                    |                  |          |                         |                      |
| 600382-5              | 0.035"   | 4200               | 130              | straight | hydrophilic, radiopaque | extra stiff ≙ 0.035" |
| HYDRO-SLIDE GUIDE WIF | RE       |                    |                  |          |                         |                      |
| MTN-BM-89/45-A        | 0.035"   | 4500               | 60               | straight | hydrophilic, radiopaque | blue-yellow          |
| MTN-BM-89/45-A-J      | 0.035"   | 4500               | 60               | J-form   | hydrophilic, radiopaque | blue-yellow          |
| MTN-BM-63/45-A        | 0.025"   | 4500               | 60               | straight | hydrophilic, radiopaque | blue-yellow          |
| MTN-BM-63/45-A-S      | 0.025"   | 4500               | 60               | straight | hydrophilic, radiopaque | extra stiff ≙ 0.035" |
| MTN-BM-63/45-A-J      | 0.025"   | 4500               | 60               | J-form   | hydrophilic, radiopaque | blue-yellow          |
| MTN-BM-63/45-A-J-S    | 0.025"   | 4500               | 30               | J-form   | hydrophilic, radiopaque | extra stiff ≙ 0.035" |
| MTN-BM-53/45-A        | 0.021"   | 4500               | 60               | straight | hydrophilic, radiopaque | blue-yellow          |
| MTN-BM-45/45-A        | 0.018"   | 4500               | 60               | straight | hydrophilic, radiopaque | blue-yellow          |

Packaging unit: Classic guide wire: 1 piece, Hydro-Slide guide wire: 2 pieces



# PLASTIC BILE DUCT STENTS

# MAXIMUM DRAINAGE, MAXIMUM HOLD

MICRO-TECH offers a comprehensive range of plastic stents for short and medium-term drainage in the bile duct. The stents are available in different shapes, lengths and diameters. Thus, the ideal stent is available for each indication. The high-quality PE-/PTFE-material of the stents ensures reliable drainage and adapts optimally

to the anatomy of the patient. Flaps at the ends of the stents also ensure a secure hold with minimal migration. For rapid and safe implantation, the stents are available both individually and on pre-loaded systems. In addition, MICRO-TECH also offers introduction-systems in all relevant sizes.

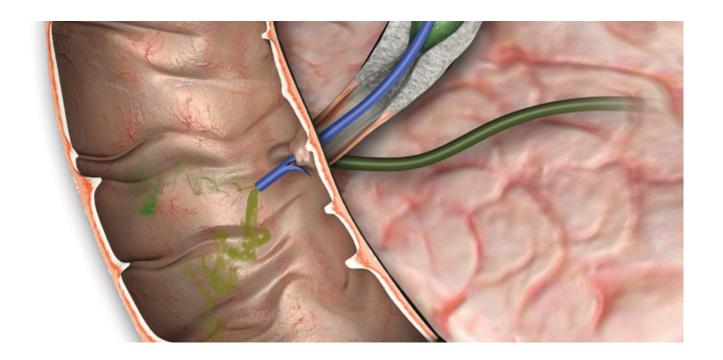
#### **SPECIFIC CHARACTERISTICS**

- Different shapes: straight, curved, angled, pigtail, double-pigtail
- Optimum flow rate
- Ideal adaptation to anatomy
- Safe hold, minimal migration
- Available single-packed or pre-loaded on introduction-system
- High x-ray visibility



Pre-loaded stent

System handle



#### **STENT STRAIGHT**



- Shape: straight
- 2 flaps
- 2 side-holes
- X-ray visible
- Material: PE

#### Diameter bile duct prosthesis

| Working length | 7 Fr.           | 8.5 Fr.         | 10 Fr.          | 11.5 Fr.        |
|----------------|-----------------|-----------------|-----------------|-----------------|
| 5 cm           | BPDS-31114-0705 | BPDS-31114-0805 | BPDS-31114-1005 | BPDS-31114-1105 |
| 6 cm           | BPDS-31114-0706 | BPDS-31114-0806 | BPDS-31114-1006 | BPDS-31114-1106 |
| 7 cm           | BPDS-31114-0707 | BPDS-31114-0807 | BPDS-31114-1007 | BPDS-31114-1107 |
| 8 cm           | BPDS-31114-0708 | BPDS-31114-0808 | BPDS-31114-1008 | BPDS-31114-1108 |
| 9 cm           | BPDS-31114-0709 | BPDS-31114-0809 | BPDS-31114-1009 | BPDS-31114-1109 |
| 10 cm          | BPDS-31114-0710 | BPDS-31114-0810 | BPDS-31114-1010 | BPDS-31114-1110 |
| 11 cm          | BPDS-31114-0711 | BPDS-31114-0811 | BPDS-31114-1011 | BPDS-31114-1111 |
| 12 cm          | BPDS-31114-0712 | BPDS-31114-0812 | BPDS-31114-1012 | BPDS-31114-1112 |
| 13 cm          | BPDS-31114-0713 | BPDS-31114-0813 | BPDS-31114-1013 | BPDS-31114-1113 |
| 14 cm          | BPDS-31114-0714 | BPDS-31114-0814 | BPDS-31114-1014 | BPDS-31114-1114 |
| 15 cm          | BPDS-31114-0715 | BPDS-31114-0815 | BPDS-31114-1015 | BPDS-31114-1115 |

# **INTRODUCER-SYSTEMS WITHOUT STENT**

## **SPECIFICATIONS**



- One step introducer-system
- X-ray visible

New: Extended guide catheter

| REF          | Ø catheter | Guide catheter | Introducer length |
|--------------|------------|----------------|-------------------|
| BPDI-0740/22 | 7 Fr.      | 40 cm          | 220 cm            |
| BPDI-0840/22 | 8.5 Fr.    | 40 cm          | 220 cm            |
| BPDI-1040/22 | 10 Fr.     | 40 cm          | 220 cm            |
| BPDI-1140/22 | 11.5 Fr.   | 40 cm          | 220 cm            |

# **INTRODUCER-SYSTEMS WITH PRE-LOADED STENT**



- One step introducer-system
- X-ray visible

## **SPECIFICATIONS**

#### **STENT STRAIGHT**



- Shape: straight
- 2 flaps
- 2 side-holes
- X-ray visible
- Material: PE

| REF                | Ø catheter | Stent working/<br>total length | Introducer length |
|--------------------|------------|--------------------------------|-------------------|
| BPDS-31114-0805/22 | 8.5 Fr.    | 5/7 cm                         | 220 cm            |
| BPDS-31114-0807/22 | 8.5 Fr.    | 7 / 9 cm                       | 220 cm            |
| BPDS-31114-0809/22 | 8.5 Fr.    | 9 / 11 cm                      | 220 cm            |
| BPDS-31114-0811/22 | 8.5 Fr.    | 11 / 13 cm                     | 220 cm            |
| BPDS-31114-1005/22 | 10 Fr.     | 5/7 cm                         | 220 cm            |
| BPDS-31114-1007/22 | 10 Fr.     | 7 / 9 cm                       | 220 cm            |
| BPDS-31114-1009/22 | 10 Fr.     | 9 / 11 cm                      | 220 cm            |
| BPDS-31114-1011/22 | 10 Fr.     | 11 / 13 cm                     | 220 cm            |

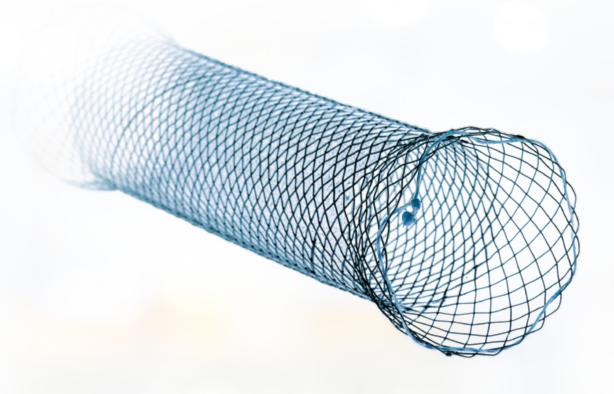
### **SPECIFICATIONS**

#### **STENT CURVED**



- Shape: 15° curved
- 2 flaps
- 2 side-holes
- X-ray visible
- Material: PE

| REF                | Ø catheter | Stent working/<br>total length | Introducer length |
|--------------------|------------|--------------------------------|-------------------|
| BPDS-32114-0805/22 | 8.5 Fr.    | 5 / 7 cm                       | 220 cm            |
| BPDS-32114-0807/22 | 8.5 Fr.    | 7 / 9 cm                       | 220 cm            |
| BPDS-32114-0809/22 | 8.5 Fr.    | 9 / 11 cm                      | 220 cm            |
| BPDS-32114-0811/22 | 8.5 Fr.    | 11 / 13 cm                     | 220 cm            |
| BPDS-32114-1005/22 | 10 Fr.     | 5/7 cm                         | 220 cm            |
| BPDS-32114-1007/22 | 10 Fr.     | 7 / 9 cm                       | 220 cm            |
| BPDS-32114-1009/22 | 10 Fr.     | 9 / 11 cm                      | 220 cm            |
| BPDS-32114-1011/22 | 10 Fr.     | 11 / 13 cm                     | 220 cm            |



# **OESOPHAGUS STENTS (GEN-I)**

# HIGHEST QUALITY FOR EVERY INDICATION

MICRO-TECH provides you with a comprehensive selection of self-expanding stents for bypassing oesophageal stenoses. The stents are characterised by very high flexibility and are available with and without covering. The

working diameter of the stent is 20. 24 or 28 mm while lengths vary of between 60 and 140 mm. Therefore, the optimum solution is always at hand for every indication.

#### **SPECIFIC CHARACTERISTICS**

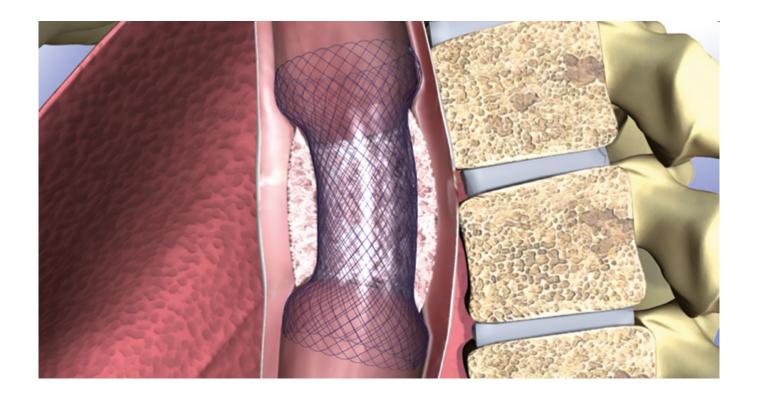
- Self-expanding
- Nitinol mesh with atraumatic ends
- Excellent positional stability
- High radial force
- Resistant and elastic covering
- Fully covered stents available
- Parylene coated
- High radiopacity
- Extraction threads for removal and repositioning
- Guide wire-compatible up to 0.035 inches







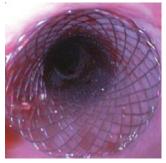
Extraction thread



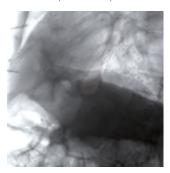
#### **SUCCESSFUL IN PRACTICAL USE**

The MICRO-TECH oesophagus stent has already proved its worth thousands of times in practice owing to its reliability, positional stability, excellent handling and the wide selection of lengths.

The stent adapts to the oesophageal wall in the best possible manner thanks to its atraumatic shape and high radial force. Furthermore, the stent possesses excellent radiopacity and can be positioned with good visibility and precision at significant points with the aid of the additional X-ray markings.



View of the proximal tulip



Released under X-ray



Control with contrast medium

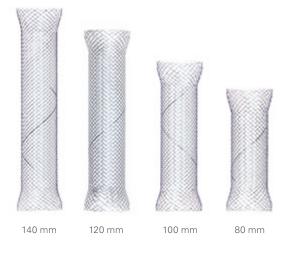


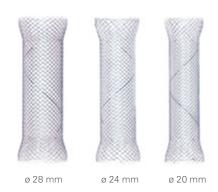
#### **POSITIONALLY STABLE STENT DESIGN**

The oesophagus stent is extremely positionally stable. Its self-expanding Nitinol wire adapts itself perfectly to the patient's anatomy and the atraumatic ends ensure a maximum hold.

#### **DIAMETERS UP TO 28 MM**

MICRO-TECH always offers you the appropriate solution with the oesophagus stent in three different diameters: 20. 24 or 28 mm in the central section. The stent end is 6 mm wider in each case.



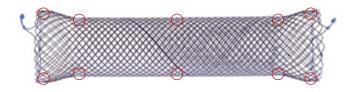


#### **NUMEROUS STANDARD LENGTHS**

Depending on the length of the site to be bypassed, you can resort to one of five standard lengths: short stents measuring 60 and 80 mm, medium lengths of 100 and 120 mm and long versions of 140 mm.

# RADIOPAQUE MARKERS FOR SECURE INSERTION OF STENTS

All of our esophagus stents are equipped with up to 10 radiopaque markers. They are clearly visible under radiological control and thus enable a secure and precise stent release.



10 X-ray markers on all significant positions

#### WITH AND WITHAOUT COVERING

Depending on the model, the stents have a protective covering. Choose between a complete covering from one stent end to the other, a partial covering in which the ends remain free and a cover-free stent.

#### INTRODUCER FOR PRECISE RELEASE

All stents are preloaded on the easy-to-manipulate introducer, which allows rapid and precise stent release. The system also allows you to bring the stent into the desired position even when in the oral cavity during release.

#### POINT OF NO RETURN

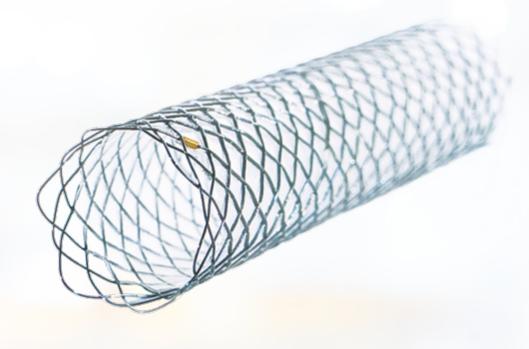
A mark on the delivery system shows the "point of no return" at stent placement.



| REF                             | Ø centre mn | n         | Ø end mm   | Length mm | Covering mm |
|---------------------------------|-------------|-----------|------------|-----------|-------------|
| STENTS WITH PARTIAL COVERING    |             |           |            |           |             |
| ST01-102.20.060                 | 20          |           | 26         | 60        | 30          |
| ST01-102.20.080                 | 20          |           | 26         | 80        | 50          |
| ST01-102.20.100                 | 20          |           | 26         | 100       | 70          |
| ST01-102.20.120                 | 20          |           | 26         | 120       | 90          |
| ST01-102.20.140                 | 20          |           | 26         | 140       | 110         |
| ST01-102.24.080                 | 24          |           | 30         | 80        | 50          |
| ST01-102.24.100                 | 24          |           | 30         | 100       | 70          |
| ST01-102.24.120                 | 24          |           | 30         | 120       | 90          |
| ST01-102.24.140                 | 24          |           | 30         | 140       | 110         |
| STENTS WITH END-TO-END COVERING |             |           |            |           |             |
| ST01-103.20.060                 | 20          |           | 26         | 60        | 60          |
| ST01-103.20.080                 | 20          |           | 26         | 80        | 80          |
| ST01-103.20.100                 | 20          |           | 26         | 100       | 100         |
| ST01-103.20.120                 | 20          |           | 26         | 120       | 120         |
| ST01-103.20.140                 | 20          |           | 26         | 140       | 140         |
| ST01-103.24.060                 | 24          |           | 30         | 60        | 60          |
| ST01-103.24.080                 | 24          |           | 30         | 80        | 80          |
| ST01-103.24.100                 | 24          |           | 30         | 100       | 100         |
| ST01-103.24.120                 | 24          |           | 30         | 120       | 120         |
| ST01-103.24.140                 | 24          |           | 30         | 140       | 140         |
| ST01-103.28.100                 | 28          |           | 34         | 100       | 100         |
| ST01-103.28.120                 | 28          |           | 34         | 120       | 120         |
|                                 |             |           |            |           |             |
|                                 | Ø mm/Fr     | Length mm | Guide wire | RM*1      | IC*2 Lock*3 |
| INTRODUCER SYSTEM               |             |           |            |           |             |
|                                 | 8/24        | 650 (SR)  | 0.035 inch | 2         | Yes Yes     |

Recommended guide wire: 600375-5

<sup>\*1</sup> RM – radiopaque markings / \*2 IC – irrigation channel / \*3 Lock – secures the introducer system during storage, transportation and introduction



# **BILIARY DUCT STENTS**

## **ALWAYS THE IDEAL SOLUTION**

With the biliary stents manufactured by MICRO-TECH you will always make the ideal choice to bridge-graft biliary duct stenoses. The high expansion force of the Nitinol wire mesh accounts for an excellent positional stability. The resistant cover prevents the stent from growing into

the tissue. The product range comprises two stent lines and offers a first-class solution that suits all requirements: the classic line and the platinum line. The comprehensive platinum line is especially distinguished by its extraordinary high radiopacity.

## **SPECIFIC CHARACTERISTICS**

- Self-expanding
- Available for TTS and PTCD
- Classic- and Platinum-Line
- Nitinol wire mesh with atraumatic ends
- Release under visual endoscopic control
- Enormous position stability
- Resistant and elastic cover
- High radiopacity
- Guiding wire passable to a maximum of 0.035 inches



X-ray marking









Endoscopic positional control



Released stent

#### **CLASSIC-LINE. FIRST-CHOICE FOR ALL APPLICATIONS**

The Classic-Line is perfectly suited for all standard interventions. With two different approaches consisting of TTS and PTCD, it perfectly meets every requirement. These stents are made of highly flexible Nitinol wire mesh. Ten additional radiopaque markers account for the good visibility of our Classic-Line stents under fluoroscopy. Our product range comprises uncovered and partially covered stents.

#### PTCD FOR PERCUTANEOUS ACCESS

In case of therapeutic interventions into the biliary duct, it sometimes occurs that a transpapillary access cannot be accomplished. In such cases MICRO-TECH offers PTCD systems (percutaneous transhepatic cholangio drainage) as the ideal solution.

#### TTS STENTS FOR ROUTINE INTERVENTIONS

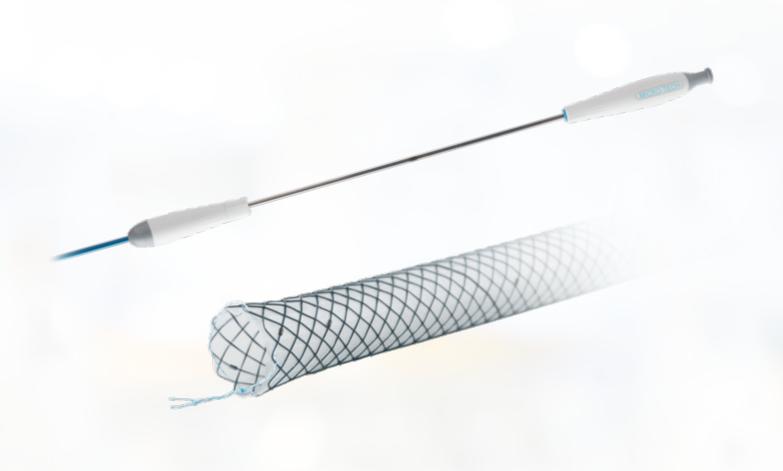
We offer uncovered as well as partially covered biliary duct stents in three different lengths. All stents can be placed through the working channel of the duodenoscope over the inserted guide wire (TTS - through-the-scope).

#### INTRODUCER SYSTEM FOR AN EXACT RELEASE

Additional radiopaque markers on the distal end of the introducer system and on the tip of the pusher catheter provide for additional orientation. In the endoscopic image, the tip of the pusher catheter can be unambiguously and easily distinguished from the proximal end of the stent. The permanent visual endoscopic control of the stent's proximal end considerably facilitates the exact release of the stent.

#### TEN PLATINUM RADIOPAQUE MARKERS

In order to achieve improved visibility under X-ray control each stent bares a total of ten radiopaque markers: four markers located at each end, and two in the middle of the stent. The two radiopaque markers in the middle guarantee for the controllability of the stent's optimal position during deployment.



# **BILIARY-STENT (GEN-II)**

# HIGH PRECISION IN SLIM DESIGN

The next generation of MICRO-TECH's biliary stents takes the bridging of bile-duct stenosis to a new level. Thanks to its slim design, the system can be pushed almost frictionless through the endoscope and released easily in the bile-duct. A high flexible, specially developed Nitinol wire and the tantalum markers ensure optimal placement under

X-ray vision. The range of stents are available in lengths from 40 to 100 mm as well as fully, partially and uncovered stents. Uncovered and partially covered variants are produced with a "point-of-no-return" that allows to re-insert the stent into the sheath again and make the repositioning much easier.

#### **SPECIFIC CHARACTERISTICS**

- Slimmer introducer set
- Point-of-no-return for uncovered and partially covered stents
- Stent system does not need to be flushed before application
- Stent with tantalum marker for good visibility under X-ray



Tantalum X-ray markings



Partly expanded

| REF                     | Ø mm             | Length mm | Working channel mm | Covering |
|-------------------------|------------------|-----------|--------------------|----------|
| STENTS STRAIGHT         |                  |           |                    |          |
| NST03-001-10.040        | 10               | 40        | 3.7                | Without  |
| NST03-001-10.060        | 10               | 60        | 3.7                | Without  |
| NST03-001-10.080        | 10               | 80        | 3.7                | Without  |
| NST03-001-10.100        | 10               | 100       | 3.7                | Without  |
| NST03-002-10.040        | 10               | 40        | 3.7                | Partial  |
| NST03-002-10.060        | 10               | 60        | 3.7                | Partial  |
| NST03-002-10.080        | 10               | 80        | 3.7                | Partial  |
| NST03-002-10.100        | 10               | 100       | 3.7                | Partial  |
| NST03-004-10.040        | 10               | 40        | 3.7                | Complete |
| NST03-004-10.060        | 10               | 60        | 3.7                | Complete |
| NST03-004-10.080        | 10               | 80        | 3.7                | Complete |
| VST03-004-10.100        | 10               | 100       | 3.7                | Complete |
| STENTS WITH EXTENDED TO | ULIPS            |           |                    |          |
| VST03-111-10.040        | 10/12            | 40        | 3.7                | Without  |
| VST03-111-10.060        | 10/12            | 60        | 3.7                | Without  |
| VST03-111-10.080        | 10/12            | 80        | 3.7                | Without  |
| VST03-111-10.100        | 10/12            | 100       | 3.7                | Without  |
| NST03-112-10.040        | 10/12            | 40        | 3.7                | Partial  |
| NST03-112-10.060        | 10/12            | 60        | 3.7                | Partial  |
| VST03-112-10.080        | 10/12            | 80        | 3.7                | Partial  |
| NST03-112-10.100        | 10/12            | 100       | 3.7                | Partial  |
| NST03-114-10.040        | 10/12            | 40        | 3.7                | Complete |
| NST03-114-10.060        | 10/12            | 60        | 3.7                | Complete |
| NST03-114-10.080        | 10/12            | 80        | 3.7                | Complete |
| NST03-114-10.100        | 10/12            | 100       | 3.7                | Complete |
|                         | Ø mm/Fr          | Length mm | Guide wire RM*1    | Lock*2   |
| INTRODUCER SYSTEM       |                  |           |                    |          |
|                         | 2.5/7.5; 2.8/8.5 | 1800      | 0.035 inch 2       | Yes      |

 $<sup>^{*}1</sup>$  RM – radiopaque markings /  $^{*}2$  Lock – secures the introducer system during transport, storage and insertion

Recommended guide wires:

Straight: MTN-BM-89/45-A, MTN-BM-63/45-A, MTN-BM-53/45-A, MTN-BM-45/45-A.

J-tip: MTN-BM-89/45-A-J, MTN-BM-63/45-A-J.

Number: 6082015CE01

# **EU Quality Management System Certificate**

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

# Micro-Tech (Nanjing) Co., Ltd.

No.10 Gaoke Third Road, Nanjing National Hi-Tech Industrial Development Zone 210032 Nanjing, Jiangsu Province

P. R. China

SRN ID.: CN-MF-000006950

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 6082014CN Additional certificate: 6126407TD01

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße, 80 20537 Hamburg, Germany

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation. 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

**DEKRA Certification B.V** 

B.T.M. Holtus Managing Director

J.M. McKenzie

Principal Certification Manager

First Issued: 16 September 2022 Date: 1 August 2023 Expiry date: 1 September 2027

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 6082015CE01

# **EU Quality Management System Certificate**

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

This certificate covers the following device(s) / groups of device(s):

Active non-implantable imaging devices utilising non-ionizing radiation (MDA0202, class IIa)

#### Device name:

- Single-Use Video Bronchoscopes
- **Digital Controllers**
- Single-Use Video Pancreaticobiliary Scopes
- PB Digital Controllers

Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools (MDN 1203, class IIa)

#### Device name:

- Sterile Biliary Stone Retrieval Balloon Catheter (including Retrieval Balloon / short-wire compatible)
- Biliary Plastic Stent Introducer (Biliary Plastic Stent Introducer, Biliary Plastic Stent Introducer/short-wire compatible)
- **Dilation Balloon**
- Disposable Multistage Dilation Balloon Catheter
- Non Vascular Sterile Hydro Slide Guidewire

#### Non-active non-implantable instruments (MDN 1208, class lla)

#### Device name:

- Extraction Basket (including Extraction Basket/short-wire compatible)
- Nitinol Spiral Extraction Basket (including Nitinol Spiral Extraction Basket/short-wire compatible)
- Injection Needle
- Single-Use SD Biopsy Forceps
- Single-Use Biopsy Forceps

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# **EU Quality Management System Certificate**

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

#### SPHINCTEROTOMES (G030402, class llb)

#### Device name:

- Sphincterotome / short-wire compatible
- Sphincterotome

Intended Purpose: The device is intended to be used with endoscope and guidewire for selective cannulation of the biliary ducts and monopolar cutting in sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi using high-frequency current. The device can also be used to inject contrast medium.

#### Esophageal Prostheses-Other (P050199, class lib implantable)

#### Device name:

- Esophageal Stent

Intended Purpose: The Esophageal Stent implant is indicated for use in the palliative treatment of esophageal stricture caused by malignant neoplasms, cardia stricture, anastomotic stoma stricture, and the esophageal fistula occluding.

Conditions for or limitations to the validity of this certificate:

N/A

#### **Certificate History**

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

| Revision | Date of Issue certificate | Certification Notice Reference | Action       |
|----------|---------------------------|--------------------------------|--------------|
| 0        | 16 September 2022         | 6082014CN02                    | /First issue |
| 1        | 20 April 2023             | 6082014CN04                    | Revised      |
| 2        | 18 July 2023              | 6082014CN06                    | Revised      |
| 3        | 24 July 2023              | 6082014CN07                    | Revised      |
| 4        | 1 August 2023             | 6082014CN08                    | Revised      |

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