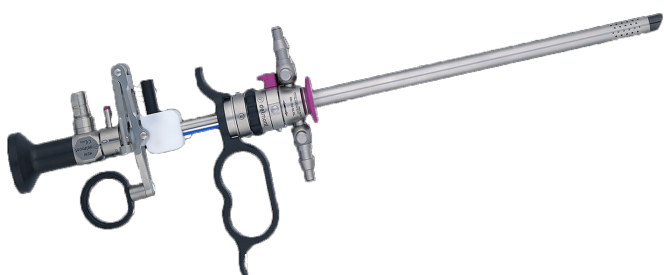


## Data sheet MaxiCare



Passive set

Ref: D400 100 008

GTIN code: 3701217802667

The complete MaxiCare set contains:

- 1 HD hysteroscope
- 1 outer sheath
- 1 inner sheath
- 1 working element
- 4 HF electrodes
- 1 light cable

Active set

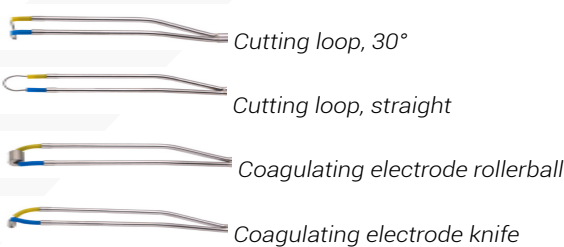
Ref: D400 100 004

GTIN code: 3701217802650

| Hysteroscope                      |                                                                                                                                                                                                                                                                                                                                            |
|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Regulation                        |                                                                                                                                                                                                                                                                                                                                            |
| Description                       | HD 4 mm 12° hysteroscope                                                                                                                                                                                                                                                                                                                   |
| Intended use                      | Gynecological and urological endoscopy only                                                                                                                                                                                                                                                                                                |
| Photo                             |                                                                                                                                                                                                                                                        |
| CE marking                        | Yes (CE 1304)                                                                                                                                                                                                                                                                                                                              |
| Device class                      | Ila                                                                                                                                                                                                                                                                                                                                        |
| Article reference                 | D300 100 002                                                                                                                                                                                                                                                                                                                               |
| GMDN code                         | 36628                                                                                                                                                                                                                                                                                                                                      |
| GTIN code                         | 3701217800182                                                                                                                                                                                                                                                                                                                              |
| Complies with European directive  | 93/42/CEE                                                                                                                                                                                                                                                                                                                                  |
| Complies with international norms | EN ISO 15223-1:2013, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 17665-1:2006, EN 1041:2008, EN ISO 10993-10:2013, EN ISO 17665-1:2006, EN 62366:2008, EN ISO 10993-12:2012, EN ISO 10993-18:2009, EN ISO 17664:2004, ISO 8600-4:2014, ISO 8600-5:2005, ISO 8600-1:2015, ISO 8600-6:2005, ISO 8600-3:1997/AMD 1:2003, ISO 8600-7:2012 |
| Toxic/allergenic products         | Latex free, DEHP free, Halogen free                                                                                                                                                                                                                                                                                                        |

| Technical data                    |                                                                                                                                                            |
|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Resolution                        | HD                                                                                                                                                         |
| Hystroscope diameter              | 4 mm                                                                                                                                                       |
| Angulation                        | 12°                                                                                                                                                        |
| Type of technology                | Lenses                                                                                                                                                     |
| Usable length                     | 300 mm                                                                                                                                                     |
| Cleaning and disinfection         | Disinfection of the endoscope according to the manufacturer's instructions, rinsing and drying. <i>See instructions for use for further details</i>        |
| Autoclavable                      | Yes                                                                                                                                                        |
| Connection for light cable        | ACMI type                                                                                                                                                  |
| Light cable adapter               | Wolf, Storz, Olympus type                                                                                                                                  |
| Environment                       |                                                                                                                                                            |
| Transport and storage temperature | -10°C / +40°C                                                                                                                                              |
| Transport and storage humidity    | 10 to 90%                                                                                                                                                  |
| Resectoscopy system               |                                                                                                                                                            |
| Regulation                        |                                                                                                                                                            |
| Description                       | Resectoscopes and associated sheaths                                                                                                                       |
| Intended use                      | Bipolar resectoscopy for gynecology and urology only                                                                                                       |
| Photos                            |  <p>Outer sheath</p> <p>Inner sheath</p> <p>Passive working element</p> |
| CE marking                        | Yes (CE 1304)                                                                                                                                              |
| Device class                      | IIb                                                                                                                                                        |
| Complies with European directive  | 93/42/CEE                                                                                                                                                  |

|                                         |                                                                                                                                                                                                                                                                                                                    |
|-----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Complies with international norms       | EN ISO 15223-1:2013, EN ISO 10993-1:2009, EN 60601-1:2006, EN 1041:2008, EN ISO 10993-10:2013, IEC 60601-2-18:2009, EN 62366:2008, EN ISO 10993-12:2012, EN ISO 17664:2004, EN 60601-2-2:2009, ISO 7153-1:2016, EN ISO 10993-18:2009, EN ISO 17665-1:2006, EN 60601-1-6:2010, EN ISO 10993-5:2009, ISO 7153-1:2016 |
| Toxic/allergenic products               | Latex free, DEHP free, Halogen free                                                                                                                                                                                                                                                                                |
| Outer sheath                            |                                                                                                                                                                                                                                                                                                                    |
| Article reference                       | D300 130 004                                                                                                                                                                                                                                                                                                       |
| GMDN code                               | 37806                                                                                                                                                                                                                                                                                                              |
| GTIN code                               | 3701217801318                                                                                                                                                                                                                                                                                                      |
| Outer sheath's diameter                 | 26Fr.                                                                                                                                                                                                                                                                                                              |
| Usable length                           | 187 mm                                                                                                                                                                                                                                                                                                             |
| Quick lock                              | Yes                                                                                                                                                                                                                                                                                                                |
| Flow                                    | Double                                                                                                                                                                                                                                                                                                             |
| Cleaning and disinfection               | Separate the internal and external sheaths beforehand. Pre-cleaning then cleaning and thermal disinfection in the machine according to the manufacturer's instructions of the solutions and machines used. <i>See instructions for use for further details</i>                                                     |
| Autoclavable                            | Yes. <i>See instructions for use for further details</i>                                                                                                                                                                                                                                                           |
| Inner sheath                            |                                                                                                                                                                                                                                                                                                                    |
| Article reference                       | D300 130 005                                                                                                                                                                                                                                                                                                       |
| GMDN code                               | 37806                                                                                                                                                                                                                                                                                                              |
| GTIN code                               | 3701217801325                                                                                                                                                                                                                                                                                                      |
| Inner sheath's diameter                 | 24Fr.                                                                                                                                                                                                                                                                                                              |
| Isolation                               | Black ceramic (4.5 mm)                                                                                                                                                                                                                                                                                             |
| Rotatable sheath                        | Yes                                                                                                                                                                                                                                                                                                                |
| Separable internal and external sheaths | Yes                                                                                                                                                                                                                                                                                                                |
| Cleaning and disinfection               | Separate the internal and external sheaths beforehand. Pre-cleaning then cleaning and thermal disinfection in the machine according to the manufacturer's instructions of the solutions and machines used. <i>See instructions for use for further details</i>                                                     |
| Autoclavable                            | Yes. <i>See instructions for use for further details</i>                                                                                                                                                                                                                                                           |

| Working element                                             |                                                                                                                                                                                                                                                                              |                        |                                  |                             |
|-------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------------------|-----------------------------|
| Action                                                      | Passive                                                                                                                                                                                                                                                                      |                        | Active                           |                             |
| Article reference                                           | D300 130 006                                                                                                                                                                                                                                                                 |                        | D300 130 008                     |                             |
| GMDN code                                                   | 37805                                                                                                                                                                                                                                                                        |                        |                                  |                             |
| GTIN code                                                   | 3701217801332                                                                                                                                                                                                                                                                |                        | 3701217801356                    |                             |
| Compatible with bipolar energies                            | Yes                                                                                                                                                                                                                                                                          |                        |                                  |                             |
| Compatible with monopolar energies                          | No                                                                                                                                                                                                                                                                           |                        |                                  |                             |
| Quick-lock between the two sheathes and the working element | Yes                                                                                                                                                                                                                                                                          |                        |                                  |                             |
| HF electrodes                                               |                                                                                                                                                                                                                                                                              |                        |                                  |                             |
| Regulation                                                  |                                                                                                                                                                                                                                                                              |                        |                                  |                             |
| Description                                                 | Reusable HF electrodes for resection system                                                                                                                                                                                                                                  |                        |                                  |                             |
| Intended use                                                | Gynecological and urological endoscopy only. Tissue removal, cutting, coagulation                                                                                                                                                                                            |                        |                                  |                             |
| Photo                                                       |                                                                                                                                                                                          |                        |                                  |                             |
| CE marking                                                  | Yes (CE 1304)                                                                                                                                                                                                                                                                |                        |                                  |                             |
| Device class                                                | IIb                                                                                                                                                                                                                                                                          |                        |                                  |                             |
| GMDN code                                                   | 42553                                                                                                                                                                                                                                                                        |                        |                                  |                             |
| Complies with European directive                            | 93/42/CEE                                                                                                                                                                                                                                                                    |                        |                                  |                             |
| Complies with international norms                           | EN ISO 15223-1:2013, EN ISO 10993-1:2009, EN 60601-1:2006, EN 1041:2008, EN ISO 10993-10:2013, IEC 60601-2-18:2009, EN 62366:2008, EN ISO 10993-12:2012, EN ISO 17664:2004, EN 60601-2-2:2009, ISO 7153-1:2016, EN ISO 10993-18:2009, EN ISO 17665-1:2006, EN 60601-1-6:2010 |                        |                                  |                             |
| Toxic/allergenic products                                   | Latex free, DEHP free, Halogen free                                                                                                                                                                                                                                          |                        |                                  |                             |
| Technical data                                              |                                                                                                                                                                                                                                                                              |                        |                                  |                             |
| Name                                                        | Cutting loop, 30°                                                                                                                                                                                                                                                            | Cutting loop, straight | Coagulating electrode rollerball | Coagulating electrode knife |
| Article reference                                           | D300 140 004                                                                                                                                                                                                                                                                 | D300 140 007           | D300 140 006                     | D300 140 005                |

|                                    |                                                                                                                                                                                                         |               |               |               |
|------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|---------------|---------------|
| GTIN code                          | 3701217802179                                                                                                                                                                                           | 3701217802209 | 3701217802193 | 3701217802186 |
| Color code                         | Yellow and blue                                                                                                                                                                                         |               |               |               |
| Compatibility                      | 26Fr. resector                                                                                                                                                                                          |               |               |               |
| Reusable electrode                 | Yes                                                                                                                                                                                                     |               |               |               |
| Generator output power             | max. 2 kVp                                                                                                                                                                                              |               |               |               |
| Recommended power cutting mode     | 120-180 W                                                                                                                                                                                               |               |               |               |
| Recommended power coagulation mode | max. 100 W                                                                                                                                                                                              |               |               |               |
| Bipolar solution to be used        | 0.9% NaCl                                                                                                                                                                                               |               |               |               |
| Cleaning and disinfection          | Pre-cleaning then cleaning and thermal disinfection in the machine according to the manufacturer's instructions of the solutions and machines used. <i>See instructions for use for further details</i> |               |               |               |
| Autoclavable                       | Yes. <i>See instructions for use for further details</i>                                                                                                                                                |               |               |               |
| Light cable                        |                                                                                                                                                                                                         |               |               |               |
| Regulation                         |                                                                                                                                                                                                         |               |               |               |
| Description                        | Light cable                                                                                                                                                                                             |               |               |               |
| Intended use                       | Endoscopy                                                                                                                                                                                               |               |               |               |
| Photo                              |                                                                                                                      |               |               |               |
| CE marking                         | Yes                                                                                                                                                                                                     |               |               |               |
| Device class                       | I                                                                                                                                                                                                       |               |               |               |
| Article reference                  | D200 150 500                                                                                                                                                                                            |               |               |               |
| GTIN code                          | 3701217800090                                                                                                                                                                                           |               |               |               |
| Complies with European directive   | 93/42/CEE                                                                                                                                                                                               |               |               |               |
| Complies with international norms  | IEC 60601-1:2005, IEC 60601-2-18:2009, DIN EN ISO 10993-1:2010-04, DIN EN ISO 10993-5:2009-10, DIN EN ISO 10993-12:2009-08, EN ISO 17664:2004                                                           |               |               |               |

| Technical data            |                                                                                                                                                                                                                                                                |
|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diameter                  | 3.5 mm                                                                                                                                                                                                                                                         |
| Length                    | 2.3 m                                                                                                                                                                                                                                                          |
| Color                     | Grey                                                                                                                                                                                                                                                           |
| Cleaning and disinfection | Pre-cleaning then cleaning and disinfection in the machine according to the manufacturer's instructions of the solutions and machines used, manual cleaning and disinfection possible but not recommended. <i>See instructions for use for further details</i> |
| Autoclavable              | Yes. <i>See instructions for use for further details</i>                                                                                                                                                                                                       |
| End caps supplied         | Storz                                                                                                                                                                                                                                                          |