

## Request Form for Custom-made medical device

Serial number

## Esophageal stent

|                                                                           |                                                                                                               |                                                                  |                                                    |
|---------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|----------------------------------------------------|
| <b>Hospital name</b>                                                      |                                                                                                               | <b>Prescribing physician name</b>                                |                                                    |
| <b>Stent details (all fields are mandatory)</b>                           |                                                                                                               |                                                                  |                                                    |
| <b>Type of stent</b><br>General information<br>Please tick all that apply | <input type="checkbox"/> Biodegradable                                                                        | <input type="checkbox"/> Nitinol                                 |                                                    |
|                                                                           | <input type="checkbox"/> Uncovered                                                                            | <input type="checkbox"/> Covered                                 | <input type="checkbox"/> Flared                    |
|                                                                           | <input type="checkbox"/> Partially covered - Please specify:                                                  |                                                                  | <input type="checkbox"/> Tubular                   |
| <b>Stent dimensions [mm]</b>                                              | Proximal flare diameter:                                                                                      | Stent body diameter:                                             | Distal flare diameter:                             |
|                                                                           | Length:                                                                                                       | Maximum stent length after deployment:                           |                                                    |
| <b>Radiopaque markers – Specify quantity</b>                              | <input type="checkbox"/> Proximal end<br>Quantity:                                                            | <input type="checkbox"/> In the middle of the stent<br>Quantity: | <input type="checkbox"/> Distal end<br>Quantity:   |
|                                                                           | <input type="checkbox"/> Proximal stent end                                                                   | <input type="checkbox"/> Distal stent end                        |                                                    |
| <b>Delivery system</b>                                                    | Diameter [F]:                                                                                                 | Length [mm]:                                                     |                                                    |
| <b>Other specification for stent and delivery system</b>                  | <input type="checkbox"/> Anti-migration collar (for Nitinol stent)                                            |                                                                  |                                                    |
|                                                                           | <input type="checkbox"/> Anti-reflux valve (for Nitinol stent)                                                |                                                                  |                                                    |
|                                                                           | <input type="checkbox"/> Other:                                                                               |                                                                  |                                                    |
| <b>Identification of patient</b>                                          |                                                                                                               |                                                                  |                                                    |
| <b>Age of patient</b>                                                     |                                                                                                               |                                                                  |                                                    |
| <b>Patient details (all fields are mandatory)</b>                         |                                                                                                               |                                                                  |                                                    |
| <b>Indication</b>                                                         | <input type="checkbox"/> Caustic stenosis                                                                     | <input type="checkbox"/> Peptic stenosis                         | <input type="checkbox"/> Postinflammatory stenosis |
|                                                                           | <input type="checkbox"/> Postsurgical stenosis                                                                | <input type="checkbox"/> Anastomotic stenosis                    | Please specify:                                    |
|                                                                           | Reason for surgery<br><input type="checkbox"/> Atresia:<br><input type="checkbox"/> Other:<br>Please specify: |                                                                  |                                                    |
|                                                                           | <input type="checkbox"/> Leak                                                                                 | <input type="checkbox"/> Fistula                                 |                                                    |
|                                                                           | <input type="checkbox"/> Other specification:                                                                 |                                                                  |                                                    |
| <b>Length of stenosis [mm]</b>                                            |                                                                                                               |                                                                  |                                                    |
| <b>Location of stenosis or lesion</b>                                     | <input type="checkbox"/> Upper esophagus                                                                      | Distance from musculus cricopharyngeus [cm]:                     |                                                    |
|                                                                           | <input type="checkbox"/> Middle esophagus                                                                     | <input type="checkbox"/> Lower esophagus                         |                                                    |

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|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| <b>Original diagnosis</b>                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                            |                      |
| <b>Treatment history</b><br>Please detail all treatment(s), procedures & management to date, maximum dilation achieved (if dilated) & potential associated risks, etc. | Previous stent implantation<br><input type="checkbox"/> Yes <input type="checkbox"/> No<br><br>Type of the stent:<br><br>Number of implantations:<br><br>Dates of implantations:<br><br>Surgery<br><input type="checkbox"/> Yes <input type="checkbox"/> No<br>Specify:<br><br>Dilation<br><input type="checkbox"/> Yes <input type="checkbox"/> No<br>Number:<br><br>Dilation up to [mm]: | Other specification: |
| <b>Reason for using this stent</b><br>Please include potential benefits & risks to patient                                                                             |                                                                                                                                                                                                                                                                                                                                                                                            |                      |

PRE-0046-P04\_EN/02

Please note that this non-official form is designed to describe the requirements of a customer which is necessary for assessment of general safety and performance requirements according to MDR 2017/745. After confirming the availability of requested product, an official **Prescription form** shall be issued.

The **Prescription form** is an official document strictly required before dispatch of any custom-made medical device!

Please note that the stent pitch numbers, thread diameter and thread crossing angle of custom made stents can cause a length tolerance of -/+ a few mm but we will manufacture the stent as accurate as possible