

Request Form for Custom-made medical device

Serial number

Tracheal stent

Hospital name

Prescribing physician name

Stent details (all fields are mandatory)

Type of stent

General information

Please tick all that apply

☐ Biodegradable uncovered☐ Nitinol covered☐ Tubular

Stent dimensions [mm]

Diameter:

Length:

Maximum stent length after deployment:

Radiopaque markers – Specify quantity

☐ Proximal end

Quantity:

☐ In the middle of the stent

Quantity:

☐ Distal end

Quantity:

Delivery system

Diameter [F]:

Length [mm]:

☐ Olive tip☐ Balloon catheter

Other specification for stent and delivery system

Identification of patient

Age of patient

Patient details (all fields are mandatory)

Indication

☐ Stenosis post-intubation☐ Stenosis post-tracheostomy☐ Congenital tracheomalacia☐ External vascular compression☐ Post-surgical stenosis

Tumor stenosis

☐ Anastomotic stenosis☐ Extraluminal☐ Intraluminal

Reason for surgery:

☐ Leak☐ Fistula☐ Other specification:

Length of stenosis [mm]

Location of stenosis or lesion

Distance from the vocal cords [mm]:

☐ Upper trachea☐ Middle trachea☐ Lower trachea

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

FIZ-III/8-21-01-LO-05/1-EN

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.