Request Form for Custom-made medical device

Serial number

Esophageal stent

Hospital name	**Prescribing physician name**

Stent details (all fields are mandatory)

Type of stent General information Please tick all that apply	☐ Biodegradable	☐ Nitinol	☐ Stainless steel
	☐ Uncovered	☐ Covered	☐ Flared
	☐ Partially covered - Please specify:		☐ Tubular
Stent dimensions [mm]	Proximal flare diameter:	Stent body diameter:	Distal flare diameter:
	Length:	Maximum stent length after deployment:	
Radiopaque markers – *Specify quantity*	☐ Proximal end Quantity:	☐ In the middle of the stent Quantity:	☐ Distal end Quantity:
Retrieval Loops (Nitinol and stainless steel stents)	☐ Proximal stent end	☐ Distal stent end	☐ On both stent ends
Delivery system	Diameter [F]:	Length [mm]:	
	☐ Olive tip	☐ Balloon catheter	
Other specification for stent and delivery system	☐ Anti-migration collar (for Nitinol and stainless steel stent) ☐ Anti-reflux valve (for Nitinol and stainless steel stent) ☐ Other:		
Identification of patient			
Age of patient			

Patient details (all fields are mandatory)

Indication	☐ Caustic stenosis	☐ Peptic stenosis	☐ Postinflammatory stenosis Please specify:
	☐ Postsurgical stenosis	☐ Anastomotic stenosis	
	Reason for surgery ☐ Atresia: ☐ Other: Please specify:		
	☐ Leak	☐ Fistula	
	☐ Other specification:		
Length of stenosis [mm]			
Location of stenosis or lesion	☐ Upper esophagus	Distance from musculus cricopharyngeus [cm]:	
	☐ Middle esophagus	☐ Lower esophagus	

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 ☐ Yes ☐ No Type of the stent: Number of implantations: Dates of implantations: Surgery ☐ Yes ☐ No Specify: Dilation ☐ Yes ☐ No Number: Dilation up to [mm]:	Other specification:
Reason for using this stent Please include potential benefits & risks to patient		

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