

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, tubular			
Stent dimensions [mm]	Diameter:		Length:	
	Maximum stent length after deployment:			
Radiopaque markers	<input type="checkbox"/> Proximal end	<input type="checkbox"/> In the middle of the stent	<input type="checkbox"/> Distal end	
Delivery system	Diameter [F]:		Length [mm]:	
Other specification for stent and delivery system				
Identification of patient				
Age of patient				
Patient details (all fields are mandatory)				
Indication	<input type="checkbox"/> Stenosis post-intubation		<input type="checkbox"/> Stenosis post-tracheostomy	
	<input type="checkbox"/> Congenital tracheomalacia		<input type="checkbox"/> External vascular compression	
	<input type="checkbox"/> Post-surgical stenosis		Tumor stenosis	
	<input type="checkbox"/> Anastomotic stenosis		<input type="checkbox"/> Extraluminal	
			<input type="checkbox"/> Intraluminal	
	Reason for surgery:			
<input type="checkbox"/> Leak		<input type="checkbox"/> Fistula		
<input type="checkbox"/> Other specification:				
Length of stenosis [mm]				
Location of stenosis or lesion	Distance from the vocal cords [mm]:	<input type="checkbox"/> Upper trachea	<input type="checkbox"/> Middle trachea	<input type="checkbox"/> 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		

PRE-0046-P05_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.