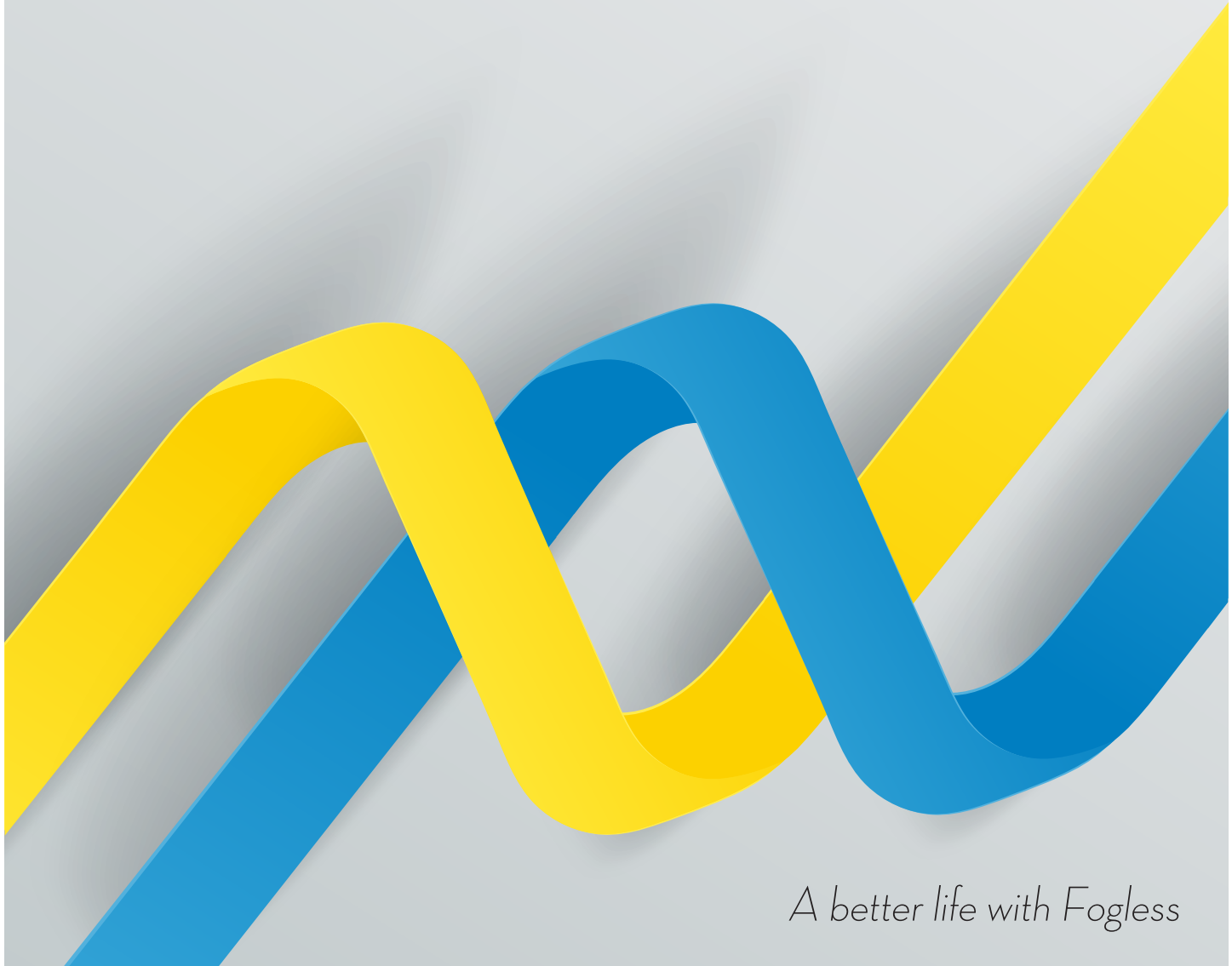




International

Catalogue 2023



A better life with Fogless






SPIRO

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	ART	DESCRIPTION	QTY
	702	<p>SPIRO 702 Humidifier is a Heat Moisture Exchange (HME) for spontaneous breathing tracheostomy users. This device provides comfortable heat and moisture to the user and prevents coarse particles from entering the respiratory system. The device has an exchangeable filter. The device housing and cover can be re-used multiple times with correct care. The user cannot speak with this device and is to be used when resting or sleeping. Supplementary oxygen can be delivered through the integrated oxygen nipple.</p>	
	702-1	<p>1 x SPIRO 702 Humidifier packaged in a polyethylene zip-lock bag.</p> <ul style="list-style-type: none"> • Bag Dimensions: 118 x 70 mm • Total Package Weight: 8 g • Sold in: 2-pack carton (702-2K), 5-pack carton (702-5K) and 20-pack carton (702-20K) 	1
	702-2K	<p>2 x SPIRO 702 Humidifiers packaged individually in polyethylene zip lock bags. Secondary packaging in a 300 gsm eco-friendly paper carton.</p> <ul style="list-style-type: none"> • Carton Dimensions: 75 x 70 x 40 mm • Total carton weight including contents: Weight: 35 g • Minimum Order: 100 devices (50 cartons) • 1 x Instructions For Use per carton 	2
	702-5K	<p>5 x SPIRO 702 Humidifiers packaged individually in polyethylene zip lock bags. Secondary packaging in a 300 gsm eco-friendly paper carton.</p> <ul style="list-style-type: none"> • Carton Dimensions: 157 x 72 x 40 mm • Total Package Weight: 67 g • Minimum Order: 100 devices (20 cartons) • 1 x Instructions For Use per carton 	5
	702-20K	<p>10 x SPIRO 702 Humidifiers packaged in polyethylene zip lock bags (x2). Secondary packaging in a 300 gsm eco-friendly paper carton</p> <ul style="list-style-type: none"> • Carton Dimensions: 175 x 175 x 35 mm • Total Package Weight: 153 g • Minimum Order: 240 pieces (12 cartons) • 1 x Instructions For Use per carton 	20




Speaking Valves

	ART	DESCRIPTION	QTY
	710	SPIRO 710 Speaking Valve with oxygen nipple for spontaneous breathing tracheostomy users. Intended to allow the user to speak without the need for finger occlusion. Also provides back pressure for other common body functions. Exchangeable filter to prevent coarse particles entering the respiratory system. The main valve housing can be re-used multiple times with correct care. When resting or sleeping the SPIRO 702 Humidifier shall be used. Supplementary oxygen can be delivered through the integrated oxygen nipple. This transparent device is recommended for use in the home care environment.	
	710-1	1 x SPIRO 710 Speaking Valve packaged in a polyethylene zip-lock bag. <ul style="list-style-type: none"> • Bag Dimensions: 118 x 70 mm • Total Package Weight: 6 g • Sold in 1-pack carton (710-1K), 2-pack carton (710-2K) and 5-pack carton (710-5K). 	1
	710-1K	1 x SPIRO 710 Speaking Valve packaged in a polyethylene zip lock bag. Secondary packaging in a 300 gsm eco-friendly paper carton. <ul style="list-style-type: none"> • Carton Dimensions: 75 x 70 x 42 mm • Total Package Weight: 25 g • Minimum Order: 60 devices (60 cartons) • 1 x Instructions For Use per carton 	1
	710-2K	2 x SPIRO 710 Speaking Valves packaged individually in polyethylene zip lock bags. Secondary packaging in a 300 gsm eco-friendly paper carton. <ul style="list-style-type: none"> • Carton Dimensions: 75 x 70 x 42 mm • Total Package Weight: 31 g • Minimum Order: 120 devices (60 cartons) • 1 x Instructions For Use per carton 	2
	710-5K	5 x SPIRO 710 Speaking Valves packaged individually in polyethylene zip lock bags. Secondary packaging in a 300 gsm eco-friendly paper carton. <ul style="list-style-type: none"> • Carton Dimensions: 157 x 72 x 42 mm • Total Package Weight: 57 g • Minimum Order: 150 devices (30 cartons) • 1 x Instructions For Use per carton 	5
	710R	SPIRO 710R Speaking Valve with oxygen nipple for spontaneous breathing tracheostomy users. Intended to allow the user to speak without the need for finger occlusion. Also provides back pressure for other common body functions. Exchangeable filter to prevent coarse particles entering the respiratory system. The main valve housing can be re-used multiple times with correct care. When resting or sleeping the SPIRO 702 Humidifier shall be used. Supplementary oxygen can be delivered through the integrated oxygen nipple. This coloured device is recommended for use in the emergency or intensive care hospital environment.	
	710R-1	1 x SPIRO 710R Speaking Valve packaged in a polyethylene zip-lock bag. <ul style="list-style-type: none"> • Bag Dimensions: 118 x 70 mm • Total Package Weight: 6 g • Sold in 1 pack carton (710-1K), 2-pack carton (710R-2K) and 5-pack carton (710R-5K). 	1

Speaking Valves

	ART	DESCRIPTION	QTY
	710R-2K	<p>2 x SPIRO 710R Speaking Valves packaged individually in polyethylene zip lock bags. Secondary packaging in an eco-friendly paper carton.</p> <ul style="list-style-type: none"> • Carton Dimensions: 83 x 72 x 42 mm • Total Package Weight: 31 g • Minimum Order: 120 devices (60 cartons) • 1 x Instructions For Use per carton 	2
	710R-5K	<p>5 x SPIRO 710R Speaking Valves packaged individually in polyethylene zip lock bags. Secondary packaging in an eco-friendly paper carton.</p> <ul style="list-style-type: none"> • Carton Dimensions: 157 x 72 x 40 mm • Total Package Weight: 57 g • Minimum Order: 150 devices (30 cartons) • 1 x Instructions For Use per carton 	5
	711	<p>SPIRO 711 Speaking Valve for spontaneous breathing tracheostomy users. Intended to allow the user to speak without the need for finger occlusion. Also provides back pressure for other common body functions. Exchangeable filter to prevent coarse particles entering the respiratory system. The main valve housing can be re-used multiple times with correct care. When resting or sleeping the SPIRO 702 Humidifier shall be used. This transparent device is recommended for use in the home care environment.</p>	
	711-1	<p>1 x SPIRO 711 Speaking Valve packaged in a polyethylene zip-lock bag.</p> <ul style="list-style-type: none"> • Bag Dimensions: 118 x 70 mm • Total Package Weight: 6 g • Sold in 1-pack carton (711-1K), 2-pack carton (711-2K) and 5-pack carton (711-5K). 	1
	711-1K	<p>1 x SPIRO 711 Speaking Valve packaged in a polyethylene zip lock bag. Secondary packaging in an eco-friendly paper carton.</p> <ul style="list-style-type: none"> • Carton Dimensions: 75 x 70 x 40 mm • Total Package Weight: 25 g • Minimum Order: 60 devices (60 cartons) • 1 x Instructions For Use per carton 	1
	711-2K	<p>2 x SPIRO 711 Speaking Valves packaged individually in polyethylene zip lock bags. Secondary packaging in an eco-friendly paper carton.</p> <ul style="list-style-type: none"> • Carton Dimensions: 75 x 70 x 40 mm • Total Package Weight: 31 g • Minimum Order: 120 devices (60 cartons) • 1 x Instructions For Use per carton 	2
	711-5K	<p>5 x SPIRO 711 Speaking Valves packaged individually in polyethylene zip lock bags. Secondary packaging in an eco-friendly paper carton.</p> <ul style="list-style-type: none"> • Carton Dimensions: 157 x 72 x 42 mm • Total Package Weight: 57 g • Minimum Order: 150 devices (30 cartons) • 1 x Instructions For Use per carton 	5

Basic Sets


	ART	DESCRIPTION	QTY
	760-1KF	<p>SPIRO Basic Set Speaking Valve – Including 1 x SPIRO 710 Speaking Valve, 1 x 702 Humidifier, 1 x 705 Tweezers, 1 x 703 Shower Protector, 1 x 730 Shower Protector. Including 1 sheet of 25 Filters (Art. 740-25).</p> <ul style="list-style-type: none"> • Packaging: Basic Set - PET Blister / Filter - PE Bag / Secondary - 300 gram paper carton • Dimensions: 175 x 175 x 42 mm • Total Package Weight: 108 g • Minimum Order: 16 sets • 1 x Instructions For Use per set 	1
	760R-1KF	<p>SPIRO Basic Set Speaking Valve – Including 1 x SPIRO 710R Speaking Valve, 1 x 702 Humidifier, 1 x 705 Tweezers, 1 x 703 Shower Protector, 1 x 730 Shower Protector. Including 1 sheet of 25 Filters (Art. 740-25).</p> <ul style="list-style-type: none"> • Packaging: Basic Set - PET Blister / Filter - PE Bag / Secondary - 300 gram paper carton • Dimensions: 175 x 175 x 42 mm • Total Package Weight: 108 g • Minimum Order: 16 sets • 1 x Instructions For Use per set 	1
	770-1KF	<p>SPIRO Basic Set Humidifier – Including 2 x 702 Humidifiers, 1 x 705 Tweezers, 1 x 703 Shower Protector, 1 x 707 Adaptor, 1 x 708 Adaptor. Including 1 sheet of 25 Filters (Art. 740-25).</p> <ul style="list-style-type: none"> • Packaging: Basic Set - PET Blister / Filter - PE Bag / Secondary - 300 gram paper carton • Dimensions: 175 x 175 x 42 mm • Total Package Weight: 105 g • Minimum Order: 16 sets • 1 x Instructions For Use per set 	1

702-20K, 740-100K, 760-1KF, 760R-1KF, 770-1KF are supplied in a paper carton as shown below:



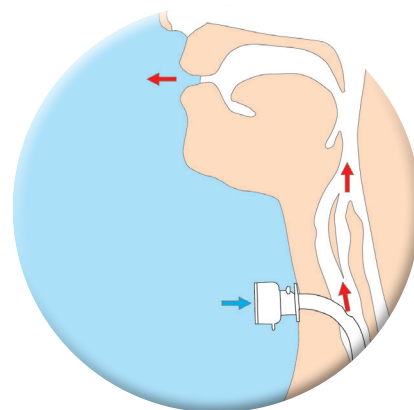
	REF	DESCRIPTION	QTY
	703	<p>SPIRO 703 Shower Protector for use with the SPIRO 702 Humidifier. Intended to prevent water splash entering the tracheostomy opening when the user is showering. Can also be used to direct warm air from the body in cold climates. Transparent in colour.</p> <ul style="list-style-type: none"> • Packaging: 2 pieces per polyethylene zip lock bag • Sold in 2-pack paper carton (article 703-2K) 	2
	705	<p>Tweezers. For use when exchanging the Filter (740) in the following: SPIRO 702 Humidifier, SPIRO Speaking Valves 710, 710R and 711.</p> <ul style="list-style-type: none"> • Packaging: 5 pieces per polyethylene zip lock bag • Length: 130 mm • Sold in 5-pack paper carton (article 705-5K) 	2
	707	<p>Adaptor for silver cannulae 13/11 mm. Transparent in colour.</p> <ul style="list-style-type: none"> • Packaging: 2 pieces per polyethylene zip lock bag • Sold in 2-pack paper carton (article 707-2K) 	2
	708	<p>Adaptor for silver cannulae 14/11 mm. White in colour.</p> <ul style="list-style-type: none"> • Packaging: 2 pieces per polyethylene zip lock bag • Sold in 2-pack paper carton (article 708-2K) 	2
	730	<p>SPIRO 730 Shower Protector for use with the SPIRO 710, 710R and 711 Speaking Valves. Intended to prevent water splash entering the tracheostomy opening when the user is showering. Can also be used to direct warm air from the body in cold climates. Transparent in colour.</p> <ul style="list-style-type: none"> • Packaging: 2 pieces per polyethylene zip lock bag • Sold in 2-pack paper carton (article 730-2K) 	2
	740	<p>SPIRO 740 Filter. Exchangeable filter which is compatible with both the SPIRO 702 Humidifier and SPIRO 710, 710R and 711 Speaking Valves. The filter prevents coarse particles from entering respiratory system.</p>	
	740-25K	<p>SPIRO 740 Filter – 1 sheet containing 25 filters. Packaged in a polyethylene zip-lock bag. Secondary packaging in a 300 gsm eco-friendly paper carton.</p> <ul style="list-style-type: none"> • Dimensions: 175 x 175 x 11 mm • Total Package Weight: 33 g • Minimum Order: 37 packs (925 filters) • Instructions for Use printed on carton 	25

Accessories

	REF	DESCRIPTION	QTY
	740-100K	<p>SPIRO 740 Filter – 4 sheets containing 25 filters each. Packaged in a polyethylene zip-lock bag. Secondary packaging in a 300 gsm eco-friendly paper carton. (see carton on pg. 6)</p> <ul style="list-style-type: none"> • Dimensions: 175 x 175 x 35 mm • Total Package Weight: 56 g • Minimum Order: 20 packs (2000 filters) • Instructions for Use printed on carton 	100
	I-025	<p>SPIRO Speaking Valve Instructions For Use (IFU). Czech, Danish, Dutch, English, Finnish, French, German, Greek, Italian, Norwegian, Spanish, Polish, Portugese, Swedish, Turkish languages. (PDF download available from fogless.se/eifu).</p>	1
	I-026	<p>SPIRO Humidifier Instructions For Use (IFU). Czech, Danish, Dutch, English, Finnish, French, German, Greek, Italian, Norwegian, Spanish, Polish, Portugese, Swedish, Turkish languages. (PDF download available from fogless.se/eifu).</p>	1





SPIRO® Speaking Valve advantages

- low inhalation resistance
- filter to prevent course particles entering the respiratory system
- three different models to suit the individual user
- unique accessories
- quiet operation and easy to maintain
- integrated oxygen nipple (710/710R)
- Made in Sweden



LAO Endotracheal tube

The LAO (Lindholm Anatomical Oval) endotracheal tube conforms to both the contour of the airway and the arytenoid cartilages. This results in safer and more comfortable intubations for the patient (delaying the need for any eventual tracheostomy), thus achieving shorter recovery times and cost savings.

	ART	DESCRIPTION	QTY
	1071	<p>1 x LAO Size 7 EO sterilised tracheal tube</p> <ul style="list-style-type: none"> • Inner diameter 6 x 8 mm; Outer diameter 9 x 11 mm • Cuff diameter 30 mm • High volume low pressure cuff • Suction lumen • Sold in 10 piece carton (1071-10K) 	1
	1071-10K	<p>10 x 1071 LAO 7 Anatomical oval tracheal tubes packaged in a white carton with EO gas indicator seal.</p> <ul style="list-style-type: none"> • Carton Dimensions: 375 x 155 x 85 mm • Total Package Weight: 448gr • Minimum Order: 10 cartons (100 devices) • 1 x Instructions for Use per carton 	10
	1081	<p>1 x LAO Size 8 EO sterilised tracheal tube</p> <ul style="list-style-type: none"> • Inner diameter 7 x 9 mm; Outer diameter 10.3 x 12.3 mm • Cuff diameter 30 mm • High volume low pressure cuff • Suction lumen • Sold in 10 piece carton (1081-10K) 	1
	1081-10K	<p>10 x 1081 LAO Size 8 Anatomical oval tracheal tubes packaged in a white carton with EO gas indicator seal.</p> <ul style="list-style-type: none"> • Carton Dimensions: 375 x 155 x 85 mm • Total Package Weight: 482gr • Minimum Order: 10 cartons (100 devices) • 1 x Instructions for Use per carton 	10

Ordering notes

1. Order quantities shall be on a per device or per piece basis.
2. All products are delivered ex-works from Vaggeryd, Sweden.
3. Delivery time 2-4 weeks after confirmation of order.
4. Terms of payment: Cash on delivery (letter of credit) or according to agreement.
5. Service fee to be added for final packaging and handling.
6. Purchase orders shall be emailed to order@fogless.se. After receipt of a new order, you will receive a reply order confirmation.

Regulatory / Quality



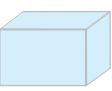
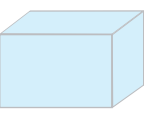
1. Fogless® is SS-EN ISO 9001:2015, SS-EN ISO 13485:2016 and SS-EN ISO 14001:2015 certified.
2. Class I products are CE marked in compliance with MDR 2017/745. Class IIa are CE marked in compliance with MDD/93/EEC and the relevant articles of MDR 2017/745.
3. All devices are cleared by FDA for sale in the USA.
4. UK Responsible Person: Fogless Ltd
5.

CH	REP
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 Swiss AR Service GmbH, Industriestrasse 47, CH-6300 Zug

Shipping Containers

Efficient quantity of devices per shipping container

	 32 x 23x 25 cm	 44 x 32 x 25 cm	 57 x 38 x 38 cm	 57 x 37 x 54 cm
702-2K	120	240	560	910
702-5K	150	300	680	1020
702-20K	240	480	1200	1800
710-1K	60	120	280	455
710-2K	120	240	560	910
710-5K	150	300	680	1020
710R-1K	60	120	280	455
710R-2K	120	240	560	910
710R-5K	150	300	680	1020
711-1K	60	120	280	455
711-2K	120	240	560	910
711-5K	150	300	680	1020
740-25K	925	1775	5000	7500
740-100K	1200	2400	6000	9000
760-1K	12	24	60	90
760R-1K	12	24	60	90
770-1K	12	24	60	90
760-1KF		16	52	78
760R-1KF		16	52	78
770-1KF		16	52	78



International



Storgatan 24, SE-567 32
Vaggeryd Sweden



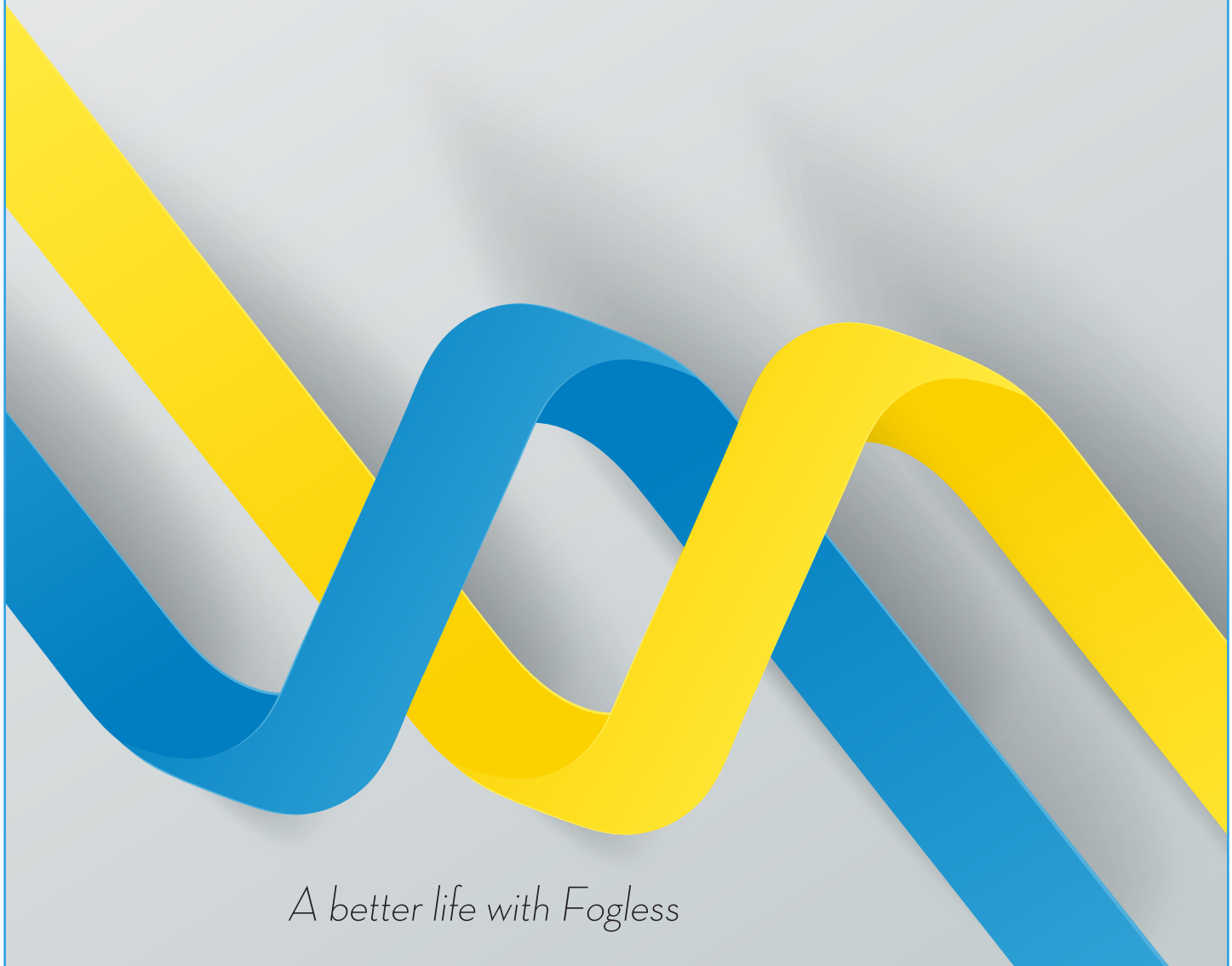
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