

## Sterile irrigation set HY-110001 Technical data sheet - Medical Device 1. Administrative information about the company Date of issue: 01/10/2015 Name: Hygitech SAS 1.1 1.2 **Phone:** +33 1 48 01 32 89 Complete address: 109 bis avenue Charles de Gaulle, Fax: +33 1 48 01 32 80 92200 Neuilly-sur-Seine e-mail: info@hygitech.fr Web site: www.hygitech.fr 1.3 **Contact information Phone:** +33 1 45 91 31 82 Materiovigilance: Claudia Régnier Fax: +33 1 48 65 67 23 e-mail: qualite@hygitech.fr 2. Information about the equipment Trade name: Sterile irrigation set 2.2 Class of MD: Class ISTERILE European Directive: 93/42/EEC including Directive 2007/47/CE According Annex n° ∨ Notified body: 0120 SGS UK LIMITED Date of first launch on the UE market: 2010\_05 Manufacturer: HYGITECH 2.3 **Product description:** With dental surgeons using two kinds of irrigation – external and internal, Hygitech offers irrigation kits that answer both needs, as well as 1-way and 2-ways systems. It is essential that the silicone tubes are compatible with the implant motors. This is why we manufacture many irrigation sets models, to offer optimum compatibility. Compatible with: FRIADENT Frios unit S / Si Surgical unit 3i NOBELBIOCARE 80 / Osseo set 100 / 200 / Osseocare STRAUMANN Zimmer Dental / Lifecore centre pulse - Innova Corp W&H Implantmed



## smart dental surgery solutions

Labelling: Unknown  2.8 Composition of the product, dimensions and accessories:    Elements	2.8	Reference HY-110001 B  Labelling: Unknow Composition of the Elements Cap Spike Tube 1 Roller clamp Connector Silicone tube Connector Tube 2 3-way stopcock	ox of 10 units  wn  e product, dime  Polyethylene  ABS  PVC  ABS  Silicone  ABS  PVC  Polycarbonate	Carton of 10 k units	cessories:  OD=4,1mm ID=	Minimum order quantity 1 box of 10 units  Dimension	
Reference	2.8	HY-110001 B  Labelling: Unknow Composition of the Elements Cap Spike Tube 1 Roller clamp Connector Silicone tube Connector Tube 2 3-way stopcock	ox of 10 units  wn  e product, dime  Polyethylene  ABS  PVC  ABS  Silicone  ABS  PVC  Polycarbonate	Carton of 10 k units	cessories:  OD=4,1mm ID=	Minimum order quantity 1 box of 10 units  Dimension	
HY-110001 Box of 10 units	2.8	Labelling: Unknot Composition of the Elements Cap Spike Tube 1 Roller clamp Connector Silicone tube Connector Tube 2 3-way stopcock	wn  e product, dime  Mar  Polyethylene  ABS  PVC  ABS  Silicone  ABS  PVC  Polycarbonate	units	Cessories :  D  OD=4,1 mm ID=	1 box of 10 units  Dimension	
Labelling: Unknown  2.8 Composition of the product, dimensions and accessories:    Elements	2.8	Composition of the  Elements  Cap Spike Tube 1 Roller clamp Connector Silicone tube Connector Tube 2 3-way stopcock	Polyethylene ABS PVC ABS Silicone ABS PVC Polycarbonate	ensions and ac	OD=4,1 mm ID=		
2.8 Composition of the product, dimensions and accessories:    Elements	2.8	Composition of the  Elements  Cap Spike Tube 1 Roller clamp Connector Silicone tube Connector Tube 2 3-way stopcock	Polyethylene ABS PVC ABS Silicone ABS PVC Polycarbonate		OD=4,1 mm ID=		
2.8 Composition of the product, dimensions and accessories:    Elements	2.8	Composition of the  Elements  Cap Spike Tube 1 Roller clamp Connector Silicone tube Connector Tube 2 3-way stopcock	Polyethylene ABS PVC ABS Silicone ABS PVC Polycarbonate		OD=4,1 mm ID=		
Cap	2.8	Elements  Cap Spike Tube 1 Roller clamp Connector Silicone tube Connector Tube 2 3-way stopcock	Polyethylene ABS PVC ABS ABS Silicone ABS PVC Polycarbonate		OD=4,1 mm ID=		
Cap		Cap Spike Tube 1 Roller clamp Connector Silicone tube Connector Tube 2 3-way stopcock	Polyethylene ABS PVC ABS ABS Silicone ABS PVC Polycarbonate	terial	OD=4,1 mm ID=:		
Spike		Spike Tube 1 Roller clamp Connector Silicone tube Connector Tube 2 3-way stopcock	ABS PVC ABS Silicone ABS PVC Polycarbonate			2,9 mm L=50 cm	
Tube 1		Tube 1 Roller clamp Connector Silicone tube Connector Tube 2 3-way stopcock	PVC ABS ABS Silicone ABS PVC Polycarbonate			2,9 mm L=50 cm	
Roller clamp ABS Connector ABS Silicone tube Silicone Connector ABS Tube 2 PVC 3-way Polycarbonate & stopcock Polyethylene Cap Polyethylene  Luer lock Male ABS Tube 1 PVC Tube 2 (x2) PVC Tube 2 (x2) PVC Tube 1 PVC Tube 1 PVC Tube 1 PVC Tube 2 (x2) PVC Tube 1 PVC Tube 2 (x2) PVC Tube 1 PVC Tube 2 (x2) PVC Tube 1 PVC Tube 1 PVC Tube 2 (x2) PVC Tube 1 PVC Tube 1 PVC Tube 2 (x2) PVC Tube 1 PVC Tube 2 (x2) PVC Tube 2 (x2) PVC Tube 1 PVC Tube 1 PVC Tube 1 PVC Tube 1 PVC Tube 2 (x2) PVC Tube 2 (x2) PVC Tube 2 (x2) PVC Tube 1 PVC Tube 2 (x2) PVC Tube 2		Roller clamp Connector Silicone tube Connector Tube 2 3-way stopcock	ABS ABS Silicone ABS PVC Polycarbonate			2,9 mm L=50 cm	
Connector   ABS   Silicone   OD=4,9mm ID=3,1 mm L=8 cm		Connector Silicone tube Connector Tube 2 3-way stopcock	ABS Silicone ABS PVC Polycarbonate				
Silicone tube Silicone OD=4,9mm ID=3,1 mm L=8 cm Connector ABS Tube 2 PVC 3-way Polycarbonate & stopcock Polyethylene Cap Polyethylene  Luer lock Male ABS ID=2,5mm  Tube 1 PVC OD=2,5mm ID=1,1 mm L=200 cm Connector Y PVC ID=2,5mm  Luer lock Male ABS ID=2,5mm  Tube 2 (x2) PVC OD=2,5mm ID=1,1 mm L=15 cm  1 way system  Luer lock Male ABS ID=2,5mm  Luer lock Male ABS ID=2,5mm  OD=2,5mm ID=1,1 mm L=100 cm  1 way system  Luer lock Male ABS ID=2,5mm  Tube 1 PVC OD=2,5mm ID=1,1 mm L=100 cm  Accessories  N-shape hook (x5) S-shape hook (x6)  Polyethylene (x6)  Presence of:  Latex Phthalates (DEHP) Products of animal or biological origin YES NO  2.9 Field - Indications: Unknown  3. Method of sterilizing  Sterile : YES		Silicone tube Connector Tube 2 3-way stopcock	Silicone ABS PVC Polycarbonate				
Connector ABS Tube 2 PVC OD=4,1mm ID=2,9 mm L=22 cm  3-way Polycarbonate & stopcock Polyethylene Cap Polyethylene  2 ways system  Luer lock Male ABS ID=2,5mm  Tube 1 PVC OD=2,5mm ID=1,1 mm L=200 cm  Tube 2 (x2) PVC ID=2,5mm  Tube 1 PVC OD=2,5mm ID=1,1 mm L=15 cm  1 way system  Luer lock Male ABS ID=2,5mm  Tube 1 PVC OD=2,5mm ID=1,1 mm L=15 cm  1 way system  Luer lock Male ABS ID=2,5mm  Tube 1 PVC OD=2,5mm ID=1,1 mm L=200 cm  Accessories  N-shape hook (x5) S-shape hook Polyethylene (x6)  [x6]  Presence of:  Latex Polyethylene [x6]  Presence of:  Latex Polyethylene [x6]  Products of animal or biological origin PYES NO  Products of animal or biological origin PYES NO  2.9 Field - Indications: Unknown  3. Method of sterilizing		Connector Tube 2 3-way stopcock	ABS PVC Polycarbonate				
Tube 2 3-way 3-way Polycarbonate & stopcock Polyethylene Cap Polyethylene  2 ways system  Luer lock Male ABS  Tube 1 Connector Y PVC Tube 2 (x2) PVC  1 way system  Luer lock Male ABS  Tube 1 PVC  Connector Y PVC Tube 2 (x2) PVC  1 way system  Luer lock Male ABS  Tube 1 PVC  OD=2.5mm ID=1,1 mm L=15 cm  1 way system  Luer lock Male ABS Tube 1 PVC  OD=2.5mm  Tube 1 PVC  OD=2.5mm  ID=2.5mm  Tube 1 PVC  OD=2.5mm ID=1,1 mm L=200 cm  Accessories  N-shape hook (x5) S-shape hook (x6)  Polyethylene (x5) S-shape hook (x6)  Presence of:  Latex Phthalates (DEHP) Products of animal or biological origin  2.9 Field - Indications: Unknown  3. Method of sterilizing  Sterile : YES		Tube 2 3-way stopcock	PVC Polycarbonate		OD=4,9mm ID=3	3,1 mm L=8 cm	
3-way Polycarbonate & Stopcock Polyethylene  Cap Polyethylene  2 ways system  Luer lock Male ABS ID=2,5mm  Tube 1 PVC OD=2,5mm ID=1,1 mm L=200 cm Connector Y PVC ID=2,5mm  Tube 2 (x2) PVC OD=2,5mm ID=1,1 mm L=15 cm  1 way system  Luer lock Male ABS ID=2,5mm  Luer lock Male ABS ID=2,5mm  Tube 1 PVC OD=2,5mm ID=1,1 mm L=10 cm  Accessories  N-shape hook (x5) S-shape hook (x6)  Polyethylene  (x6)  Presence of:  Latex YES NO  Phthalates (DEHP) YES NO  Products of animal or biological origin YES NO  2.9 Field - Indications: Unknown  3. Method of sterilizing  Sterile : YES		3-way stopcock	Polycarbonate				
Stopcock   Polyethylene   Cap   Polyethylene		stopcock			OD=4,1mm ID=2	2,9 mm L=22 cm	
Cap				€ &			
Luer lock Male   ABS   ID=2,5mm		Сар					
Luer lock Male ABS   ID=2,5mm    Tube 1			готусттуюте	2 wavs system	า า		
Connector Y PVC   ID=2,5mm   Tube 2 (x2) PVC   OD=2,5mm ID=1,1 mm L=15 cm      1 way system		Luer lock Male	ABS	,,			
Connector Y PVC   ID=2,5mm   Tube 2 (x2) PVC   OD=2,5mm   ID=1,1 mm L=15 cm    1 way system   Luer lock Male   ABS   ID=2,5mm   Tube 1   PVC   OD=2,5mm   ID=1,1 mm L=200 cm    Accessories   N-shape hook   Polyethylene   (x5)   S-shape hook   Polyethylene   (x6)    Presence of :  Latex   YES   NO   Phthalates (DEHP)   YES   NO   Products of animal or biological origin   YES   NO   Products of sterilizing   Sterile : YES		Tube 1	PVC.		OD=2,5mm ID=	1,1 mm L=200 cm	
1 way system  Luer lock Male ABS Tube 1 PVC OD=2.5mm ID=1,1 mm L=200 cm  Accessories  N-shape hook (x5) S-shape hook (x6)  Presence of:  Latex					ID=2,5mm		
Luer lock Male ABS Tube 1 PVC OD=2,5mm  Accessories  N-shape hook (x5) S-shape hook (x6)  Polyethylene (x6)  Presence of:  Latex Phthalates (DEHP) Products of animal or biological origin  2.9 Field - Indications: Unknown  Sterile: YES		Tube 2 (x2)	PVC		OD=2,5mm ID=	1,1 mm L=15 cm	
Tube 1 PVC OD=2,5mm ID=1,1 mm L=200 cm  Accessories  N-shape hook (x5) S-shape hook (x6)  Presence of:  Latex Products of animal or biological origin  2.9 Field - Indications: Unknown  Sterile : YES  OD=2,5mm ID=1,1 mm L=200 cm  Accessories  N-shape hook (x6)  Presence of:  Latex NO Presence of:  YES NO NO NO Sterile : YES				1 way system	1		
Accessories  N-shape hook (x5) S-shape hook (x6)  Polyethylene  Presence of:  Latex Phthalates (DEHP) Products of animal or biological origin  2.9 Field - Indications: Unknown  Sterile: YES  Accessories  Prolyethylene  YES NO Polyethylene  YES NO NO NO Sterile: YES					-		
N-shape hook (x5) S-shape hook (x6)  Presence of:  Latex Phthalates (DEHP) Products of animal or biological origin  2.9 Field - Indications: Unknown  Sterile: YES  No  Sterile: YES		Tube 1	PVC		OD=2,5mm ID=	1,1 mm L=200 cm	
(x5)   S-shape hook (x6)   Polyethylene			T =	Accessories			
Presence of:  Latex Phthalates (DEHP) Products of animal or biological origin  2.9 Field - Indications: Unknown  Sterile: YES  Sterile: YES		· ·	Polyethylene				
Presence of:  Latex Phthalates (DEHP) Products of animal or biological origin  2.9 Field - Indications: Unknown  3. Method of sterilizing Sterile: YES			Polyethylene				
Latex Phthalates (DEHP) Products of animal or biological origin  2.9 Field - Indications: Unknown  3. Method of sterilizing Sterile: YES							
Phthalates (DEHP) Products of animal or biological origin  2.9 Field - Indications: Unknown  3. Method of sterilizing Sterile: YES							
Products of animal or biological origin YES NO  2.9 Field - Indications: Unknown  3. Method of sterilizing  Sterile: YES		Latex			☐ YE	S NO	
2.9 Field - Indications: Unknown  3. Method of sterilizing  Sterile: YES		Phthalates (DEH	P)		⊠ YE	S NO	
3. Method of sterilizing  Sterile: YES				origin	YE	S NO	
Sterile: YES			s: Unknown				
	3. Method of st						
			<b>nd:</b> Fthvlene ∩vi	de (FO)			
4. Storage conditions	4. Storage con		ed. Littylotto OAI	~~ (LO)			
Normal conditions of storage: Store in a dry environment. The product must be		Normal conditions of storage: Store in a dry environment. The product must be					
stored in a room with a humidity rate under 80% and equipped with a ventilating		stored in a room with a humidity rate under 80% and equipped with a ventilating					
system		system					
		Special precautions: Keep this product away from direct sunlight					
Shelf life: 3 years			oraturo indicata	wee NO			
Presence of temperature indicators: NO  5. Safety in use	5 Safety in use		erature indicato	<b>лъ.</b> NO			
	5.1		v: N/A				
5.1 Technical security: N/A	5.2	Biosecurity: N/A					



6. Advices of use				
	Refer to the manual for more information on the instructions for use, indications, precautions and contra-indications			
7. Additional product information				
	Single use: YES			
8. Related documents				
	Unknown			