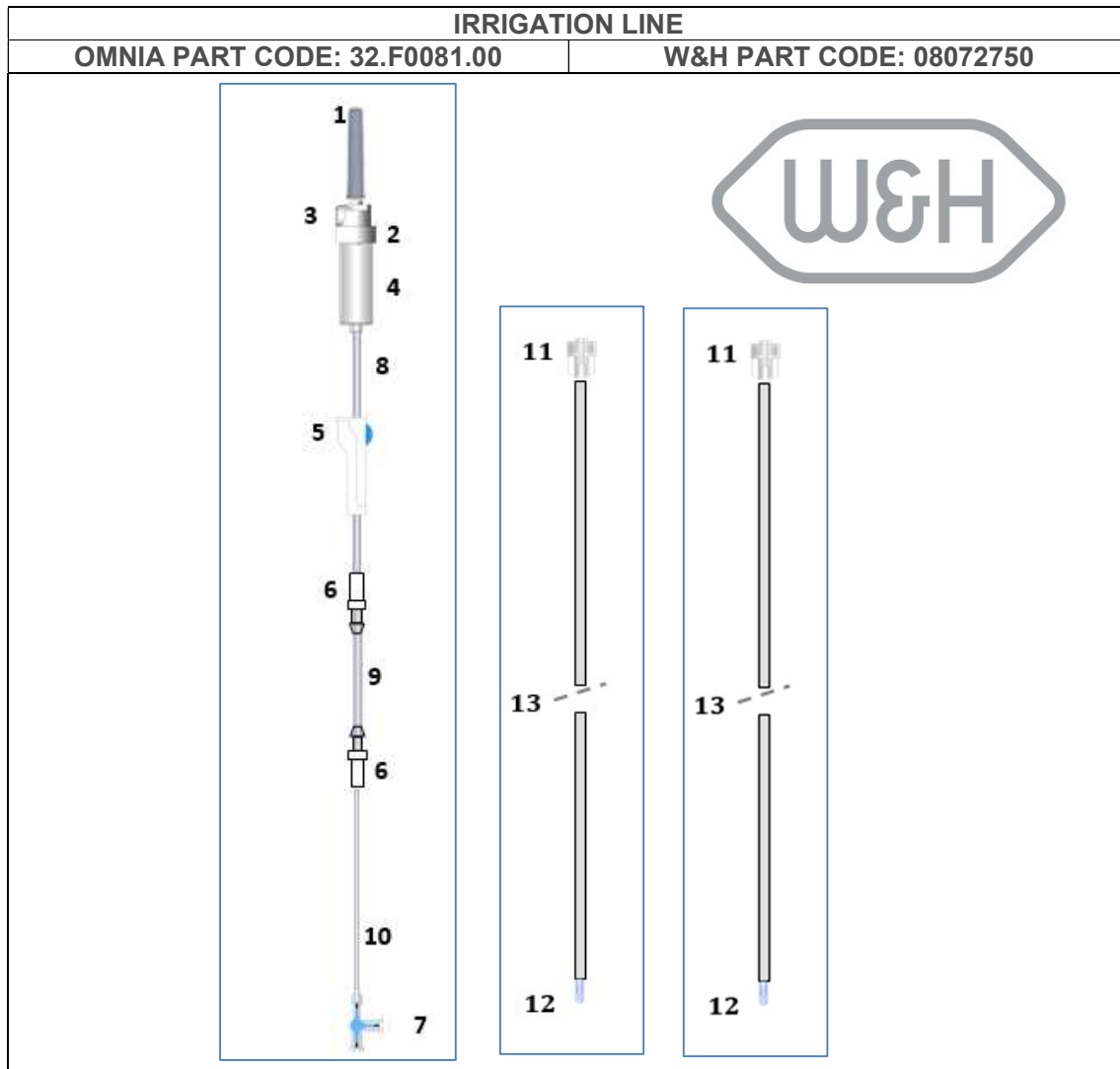


Product Data Sheet



Product Information

Manufacturer information: Omnia Srl Via F. Delnevo, 190 43036 Fidenza (PR) Italy www.omniaspa.eu	Distributor information: W&H Dentalwerk Burmoos 5111 Werner-Glaser-Straße 53 Austria www.wh.com
Description	Y-switches with 2,2 m hose each
Contains	Blister 1 pc
Sterilization Information	ETO – validity 5 years
Shelf Life	5 years
Country of Origin	Italy

Regulatory Information - EU	
Medical Device Status	Yes
Classification	Ila
Basic UDI-DI	805664650TF06EU
GMDN Term	47890
EMDN Term	A03040299
Registration Number	2147486
Custom Code	90184990
Intended Use	<p>Irrigation and washing of surgical sites and cooling of the rotary instruments used in the oral cavity during surgical or control and preventive procedures, by connecting the device to the dedicated peristaltic pump. The correct method of use of the „irrigation systems“ can be found in the Instrument Sheet of the product in question.</p> <p>The „irrigation systems“ must be connected to a micromotr/physiodispenser by means of the peristaltic pump available at the dental offices.</p>

Certificate CE	Declaration de conformity	IFU	MSDS
<i>OMNIA CE0546</i>	<i>Yes at each lot release</i>	<i>Yes</i>	<i>No</i>


Material Information	
N.	Component description
1	Vented cap for spike
2	White vented spike
3	Blue air filter for spike
4	Drip chamber
5	Roller clamp with blue wheel
6	Silicone pump connetor
7	Stopcock 3 ways
8	Irrigation tube
9	Peristaltic pump irrigation tube – silicone
10	Irrigation tube
11	Male Luer Lock connector
12	End cap- transparent terminal fitting
13	Irrigation tube green

Packaging Information		
Primary Packaging (no selling unit)		
Blister	25 x 11,6 cm	1 pc
Secondary Packaging (selling unit)		
Box	23 x 12 x 11 cm	6 pcs
with n° 1 label (dimensions 10 x 15 cm)		
Outer Packaging (transport unit)		
Carton box	80 x 59 x 42 cm	45 x 6 = 270 pcs
with n° 1 label (dimensions 10 x 15 cm)		
Pallettization		
8 carton boxes - EPAL 120x80 cm		2.160 pcs

Labeling Information

Primary Label

Vertrieb / Distributor / Distribuidor
Distributeur / Distributore:



W&H Dentalwerk Bürmoos GmbH
Ignaz-Glaser-Strasse 53,
5111 Bürmoos, Austria

T. +43 (0) 6274 6236-0
T. +43 (0) 6274 6236-55
E. office@wh.com
wh.com


Ref. 30.C1143.00- rev 00 03/2021


PEEL-OPEN


Manufacturer
Omnia Srl
Via F. Delnevo, 190
43036 Fidenza (PR) - Italy
www.omniaspa.eu


CE 0546 **MADE IN ITALY**


do not reuse do not reinsert


 **RHT**
DEHP-free


 **STERILE EO**
Sterilized using Ethylene Oxide


 **LATEX FREE**

 **Keep dry**

 **Keep away from sunlight**

 **R Only**
Caution: dental use
to suit by or on the
order of a surgeon




 **Do not use if packaging is damaged**

 **Consult instructions**

REF 32.F0081.00

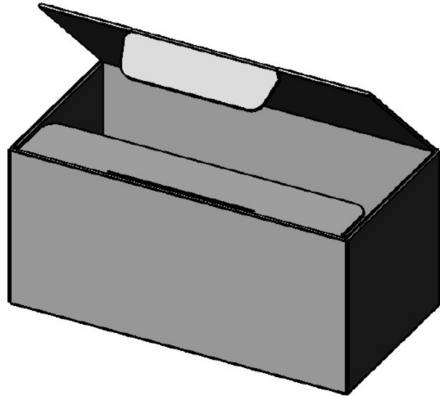
Order Code 08072750

Y-Weiche mit je 2,2 m Schlauch
Y-switches with 2,2 m hose each
Raccordo a Y con tubi da 2,2 m ciascuno
Raccord en Y avec 2,2 m de tuyau chacun
Racor en Y con 2,2 m de manguera cada uno

 2021-08-31
 **LOT** 21083101
 2026-08-31

FACSIMILE

Secondary Label



Vertrieb / Distributor / Distributore / Distributeur / Distribuidor:

W&H Dentalwerk Bürmoos GmbH
Ignaz-Glaser-Straße 53, 5111 Bürmoos,
Austria
t +43 (0) 6274 6236-0
f +43 (0) 6274 6236-55
e office@wh.com
wh.com



REF 32.F0081.00

Order code: 08072750

Manufacturer:
OMNIA Srl
Via F. Delnevo 190
43036 Fidenza
(Parma) - Italy

Y-Weiche mit je 2,2 m Schlauch
Y-switches with 2,2 m hose each
Raccordo a Y con tubi da 2,2 m ciascuno
Raccord en Y avec 2,2 m de tuyau chacun
Racor en Y con 2,2 m de manguera cada uno

6 pcs

 2021.03.31

LOT 21033101

 2026.03.31

Logistic Code:



08072750 / 21033101

Rev.01 06/2021



Sterilized using
Ethylene Oxide



Latex
free



DEHP-free



Caution



Medical
device



CE marking
0546



Do not use
if package
is damaged



Do not
resterilize



Do not
reuse



Keep dry



Keep away
from sunlight



Caution: federal law restricts
this device to sale by or
on the order of a surgeon



(01)08056646508501 (17)260331 (10)21033101 (91)32.F0081.00 (30)6

Outer Label

Vertrieb / Distributor / Distributore / Distributeur / Distribuidor:
W&H Dentalwerk Bürmoos GmbH
Ignaz-Glaser-Straße 53, 5111 Bürmoos, Austria
t +43 (0) 6274 6236-0
f +43 (0) 6274 6236-55
e office@wh.com
wh.com



REF 32.F0081.00

Order code: 08072750

Y-Weiche mit je 2,2 m Schlauch
Y-switches with 2,2 m hose each
Raccordo a Y con tubi da 2,2 m ciascuno
Raccord en Y avec 2,2 m de tuyau chacun
Racor en Y con 2,2 m de manguera cada uno
270 pcs

Manufacturer:
OMNIA Srl
Via F. Delnevo 190
43036 Fidenza
(Parma) - Italy



2021.03.31

LOT 21033101

2026.03.31



Rev.01 06/2021

(01) 08056646508549 (17) 260331 (10) 21033101 (91) 32.F0081.00 (30) 270

STERILE EO				MD CE	0546
Sterilized using Ethylene Oxyde	Latex free	DEHP free	Caution	Medical device	CE marking
					R_x Only
Do not use if package is damaged	Do not resterilize	Do not reuse	Keep dry	Keep away from sunlight	Caution: federal law restricts this device to sale by or on the order of a surgeon



(17) 260331 (10) 21033101 (91) 32.F0081.00 (30) 270

Sterilization Parameters

The validation process to determine the lethality of the cycle is the overkill method. It has been chosen between the procedures suggested by referring standard UNI EN ISO 11135-2014. This approach, substantially conservative, is based on the inactivation of referring microorganisms in conditions more critical than the used in routinely sterilization cycles. Practically the method furnished an overkill, considering that the conditions that are lethal the referring microbial charge are stronger than the conditions necessary to destroy the bioburden of product. The procedure uses half time cycles, cycle with an half exposure than normal full time. As established by SterilVerona, the biological performance qualification consists in:

- products bioburden evaluation;
- sterilization efficacy verify using referring biological indicators;
- sterility test of the products.
- test of gas residual.

The S.A.L. (Sterility Assurance Level) obtained after the sterilization is equal to 10⁻⁶.

The validation of the Sterilization is performed according to the standards:

- ISO 11135:2014 Sterilization of health care products -- Ethylene oxide
- ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods Part 2: Tests of sterility performed in the validation of a sterilization process.
- EN ISO 11138-1:2006 Sterilization of healthcare products - Biological indicators - Part 1: Biological indicators for ethylene oxide sterilization processes
- EN ISO 11138-2:2009 Sterilization of healthcare products - Biological indicators - Part 2: General requirements
- EN ISO 10993-7:2008 Biological evaluation of medical devices - part 7: Ethylene Oxide sterilization residuals

Rev	Date	Modify	Em.	Ap.
01	21.12.2020	First emisison	QA	GM
02	31.03.2021	Labels update	QA	GM
03	29.09.2021	PDS data update	QA	GM
04	11.01.2022	Labels update	QA	GM
05	17.01.2022	Packaging and Material Information update	QA	GM

