MIXPAC[™] Two-Component System 18 to 75mL





FILLING GUIDELINE Version 1.1



DENTAL



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1 General

1.1 SCOPE OF CONTENT

This document is intended as a general guideline for the process of filling and piston insertion. The information within provides a solid foundation to achieve high quality results. The guideline is applicable to manual operation as well as automated filling lines but the result of the filling process must in either case be verified by the customer (storage and application).

medmix provides the system. The receiving party shall be responsible and liable for the usage of the system and the materials applied therewith .



NOTE

In case of system compatibility issues, please do not hesitate to contact your local medmix Sales Manager.

We are grateful for any improvements suggestions and all constructive comments.

1.2 SYSTEM NAME

MIXPAC[™] Two-Component System 18 to 75mL

1.3 SYSTEM PROVIDER

medmix Switzerland AG Ruetistrasse 7 9469 Haag Switzerland Tel.: +41 81 414 70 00

E-Mail: mixpac@medmix.com

www.medmix.swiss/dental



1.4 TERMINOLOGY

The following terms are used in this filling guideline: Multicomponent Cartridge Systems; Cartridge, Plunger, Pistons, Cap Piston setting equipment; Air venting profile (AVP) aka venting shim Dispensing (discharge material from the cartridge through the mixing tip– using a dispenser)

1.5 SYMBOLS

Please observe the meaning of the following symbols:



Topic

CAUTION

NOTE

Please be aware of possible system failure if instructions are not followed.

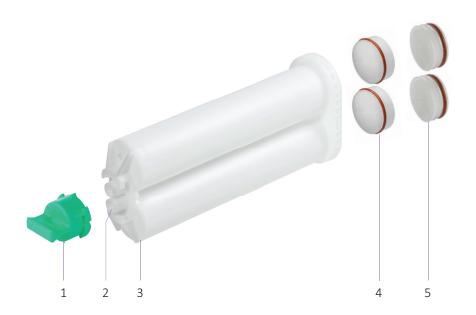


Additional information for specific application

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2 System Overview

The application system consists of a multicomponent cartridge with preinstalled cap and matching pistons.



- 1. Cap
- 2. Separated outlets
- 3. Cartridge
- 4. Pistons with o-ring
- 5. Pistons with lip and o-ring



Please refer to the MIXPAC[™] Dental Products catalogue for detailed information.

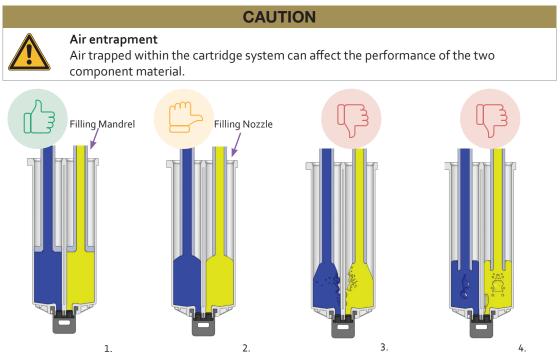
NOTE



Basic Cartridge Filling Techniques

Air trapped within the cartridge system can drastically degrade the performance of the two component material. The air inhibits the ability of the cartridge to meter the A- and B-side materials accurately because the air behaves like a shock absorber leading to a few problems; lead lag issues, poor mixing in the static mixer, and cross contamination.

The difficulty inherent with filling a cartridge air free can be mitigated by using sound techniques and properly designed equipment. Some basic techniques and/or ideas are shown below.



- 1. A properly made filling mandrel fits tightly to the inner diameter of the cartridge and provides the most effective means of filling. It allows a small amount of air to escape from the side. The material is pumped through the mandrel and the cartridge is pushed off the mandrel. In this scenario it is easy to add a limit switch to control the filling height. Additionally, it takes the control away from the operator as you will see in scenarios below.
- 2. Using a standard size filling nozzle is OK but is not as reliable as the situation found using a filling mandrel. The speed at which the filling nozzle is removed must be timed with the flow rate to minimize the risk of air entrapment. This setup works best if one is using a premeasured shot based system to fill the cartridge.
- 3. In this scenario the filling nozzle is moving faster than the material is deposited. It often leads to a large air bubble trapped towards the wall of the cartridge tube. With lower viscosity materials this scenario will create many very small bubbles as the fluid entering the chamber is very turbulent and entraps air.
- 4. In this scenario the filling nozzle is moving slower than the material is deposited. The material engulfs the end of the filling nozzle and creates a void as the nozzle is pulled from the cartridge. It often leads to large air bubbles being trapped at the center of the tube.



4 Quality of the Fill

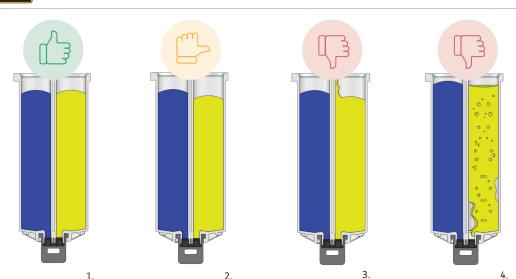
It is very important that the A and B materials are filled to equal levels to insure the proper ratio can be achieved. If the materials are filled to different heights it drastically increases the likelihood of an off-ratio condition, cross contamination, disappointment from an end user, and possibly environmental waste. Below are some examples of some filled cartridges ranging from ideal to poor. These examples are intended to be used as a general guideline to achieving high results with your filling challenges.

CAUTION



Filling Level Equilibrium

Uneven filling levels and or filling surface might lead to air entrapment at the piston.



- 1. Both of the filling levels in the first scenario are equal, there is no air trapped within the material and the profile at the top of both A- and B-sides filling is slightly domed upwards.
- 2. In this scenario it can be seen that the filling heights are not equal as there is more blue material than yellow. This indicates that the process is neither accurate, nor repeatable. It will create a risk for cross contamination and lead lag problems at the start of dispensing the cartridge. However, there are no air-bubbles trapped in the material and is therefore rated OK.
- 3. In this scenario the filling is littered with small air bubbles that may not collect (dependent on filling viscosity). The presence of the air bubbles will cause metering problems. The filling profile for the yellow side is very poor and material at the upper left edge of the cartridge could inhibit the sealing function of the piston lips. Users are advised to avoid this.
- 4. In this scenario there is a large air bubble trapped on the B-side which will cause metering problems. Also, the profile of the B-side filling is concave and might inhibit the pistons ability to vent all of the air. Again, this type of scenario will produce poor metering results and should be avoided.



See also " Effects of air inclusions - Multicomponent cartridge system"

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Piston Insertion

18 to 75 mL cartridge systems can be filled from the front as well from the back. Influencing factors are piston design, filling media viscosity as well as process capabilities/ degree of automation. In each case it must be ensured to fully evacuate the air trapped between the piston and the filling.

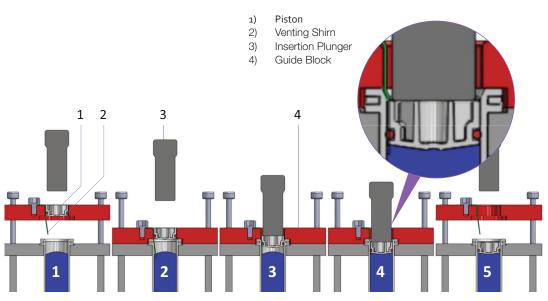
The sections below lists the factors to be considered for an air-free filling process, without contaminating and/or damaging the sealing features. The illustrations show a generic multicomponent system 50 mL cartridge system.

CAUTION



SEALING FEATURES

Damage to or contamination of the sealing features will subsequently lead to leakage during transportation or storage of the filled cartridges and/or system failure upon usage.



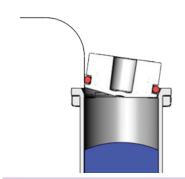
- 1. Install cartridge into a properly designed guide block and then place piston into said block so that it's rib structure can be seen from the top. The piston should fit down into the block and be square with the cartridge.
- 2. The guide block will press down onto the cartridge clamping it into place. Additionally, a venting shim will be guided into the cartridge.
- 3. Push the insertion plunger down forcing the piston into the cartridge body.
- 4. Carefully keep pushing the plunger until all of the air is evacuated. No material should leak along the shim.
- 5. The Insertion Plunger returns back to the home position. The guide block also returns and pulls the venting shim from between the cartridge and the piston.

Some highly automated equipment use vacuum technology to evacuate the air below the piston. This makes the use of a shim redundant and eases the process. Please refer to "Manufacturers of filling equipment" to identify an experienced partner in your area.



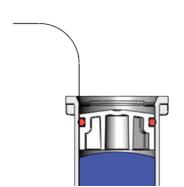
Common Piston Insertion Problems

Below are some further examples of common filling scenarios that will be encountered in any organization. Even further below there are explanations of each scenario and how to possibly rectify and/or avoid the situation as they are not ideal.



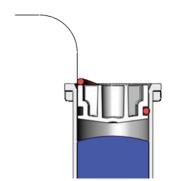
Leaking Cartridge

Never try and insert the piston at an angle as it can lead to damage to the sealing features. If the O-ring becomes damaged the cartridge will likely leak either in storage or during dispensing. It is always best to use a guide block and/or setting device.



Piston not functioning correctly

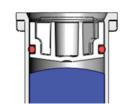
The piston in this scenario is upside down. The piston will not function correctly if oriented in this direction. The correct orientation can be identified by checking for the pistons rib structure.



O-ring disengages from original groove

The O-ring has rolled out of the original groove during insertion. Normally this will result in a leak. The piston should be removed and replaced with a new one.



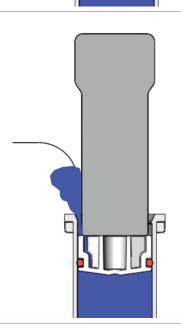


Air is not able to escape

This scenario shows that the piston has been inserted into the cartridge such that not all air was allowed to escape from underneath the piston. This cartridge will likely not meter accurately leading to poor performance of the two component material. See also "Multicomponent systems - Effects of air inclusion"

Overfilling cartridge

Do not overfill the cartridge as it may leak and/or not fit into the dispensing tool.



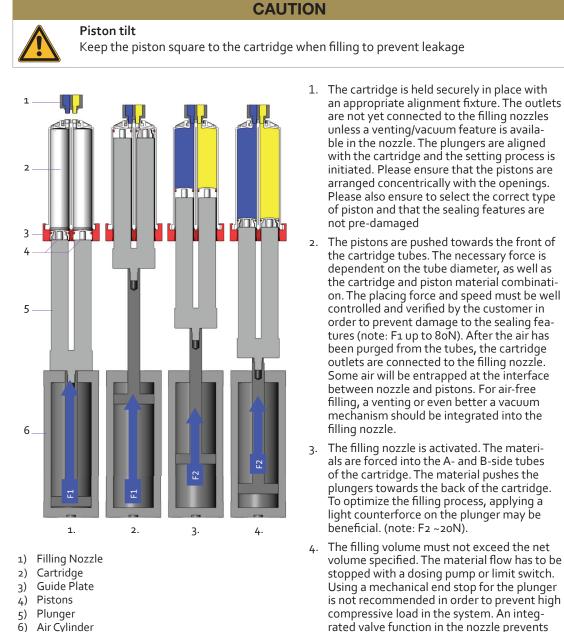
Material leakage beyond the O-ring seal

In this scenario the plunger pushes too long and/or with too much force on the material such that it pushes up beyond the O-ring seal. Some fillings will tolerate small amounts of material getting past the seal but others will not.

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Front Filling

medmix does not promote nose filling but it can be an applicable process under certain circumstances for cartridges sizes up to 50 mL. Below is a representation of a well-designed nose filling process.

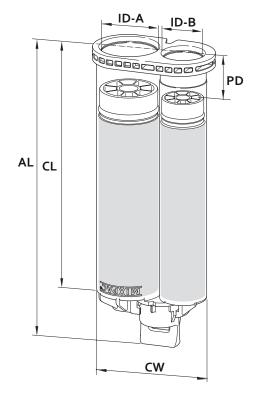


material overflow and contamination of the

sealing features.

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8 Filling Volume



AL	Assembly length		
CL	Cartridge length		
CW	Cartridge width		
ID-A	Inner diameter A-side		
ID-B	Inner diameter B-side		
PD	Piston depth		

Size [ml]	Ratio	CL [mm]	AL [mm]	CW [mm]	ID-A [mm]	ID-B [mm]	PD [mm]	
18	1:1	46	66.2	44.6	19.1	19.1		
25	1:1	78	99	37.5	15.8	15.8		
30	1:1	67	87.6	44.6	19.1	19.1		
50	1:1	102	122.6	44.8	19.1	19.1	≥3	
	2:1	102	104	44.9	22.2	15.7		data
	4:1	102	112	43.6	24.2	12.1		source: internal data
	10:1	103	122.6	43.6	13.3	6.65		e: int
75	1:1	148	168	44.8	19.1	19.1		sourc

The dimensional information contained within this table is meant as a guideline. Valid information for the specific system in use (system drawing) can be requested from your local medmix Sales Manager.

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9 Large Air Inclusions

Air trapped within the cartridge system can drastically reduce the performance of a two component material. The air inhibits the ability of the cartridge to deliver an accurate ratio between the A- and B-side materials. As the air behaves like a shock absorber, it can cause one or several of the following problems; lead lag issues, poor mixing, cross contamination and hence, potential degradation of the two component material.

Please refer to the separate info sheet for an illustrated description of the mechanics. The customer hast to verify the amount of air entrapped in the system by his filling process as well as the effects of the latter on the mixing quality.

10 Technical Data

The technical data needed for your cartridge system might differ due to filling material specific needs. Please contact your local medmix sales manager in order to provide you the necessary information for your application.

11 AvailableTools and Drawings from medmix

In order to vent pistons medmix offers venting shims (AVP's) for various cartridge diameters. Also basic piston setting tools (manual and pneumatic) are available from partners. Please contact your local medmix MIXPAC sales manager in order to provide you the necessary information for your application.

12 Applicable Documents

Effects of air inclusions - Multicomponent cartridge system Manufacturers of Filling Equipment - Dental Products

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