

ENHANCE DELIVERY

pMDI Guidance System Mouthpiece

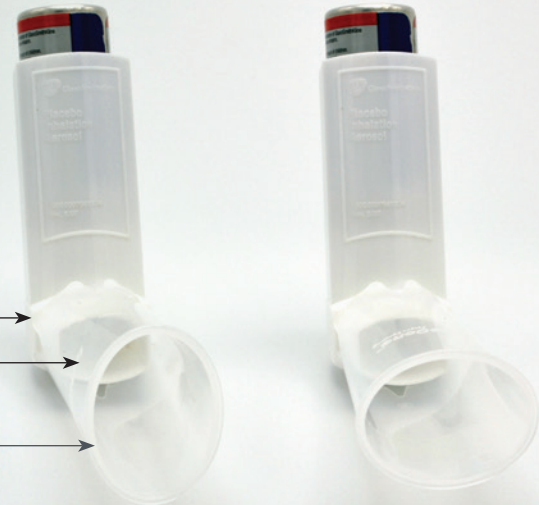


Alliance

TECH MEDICAL

InFloCone™

- **Guidance Grip™ Technology:** One size fits all.
- **Coneoval™ Shape:** Pre-set open mouth for consistent delivery.
- **Rolled Coneoval™ Edge:** For a confident seal with your lips.



Vertical Preference

Horizontal Preference



Straight-Forward Guidance

InFloCone (IFC) disposable mouthpiece is designed to simply and economically provide the user with consistent and efficient delivery when inhaling pressurized, metered dose medications.

Studies show that as many as 79% of patients could be misusing their inhalers.*

The IFC will help to avoid the random mishaps and effects of medicine spray into your face. It will also allow the momentum of high speed propelled aerosol to slow as you inhale while adding a degree of repeatability to the delivery of each dose.

- **Straight-Forward Delivery Guidance:**
 - Aids coordination so user can concentrate on inhalation technique.
 - IFC allows for propelled medication to be received more slowly.
- **Economical:**
 - Smaller size and lower cost help to build compliance and adherence to therapy.
 - Far less expensive than a Holding Chamber.
- **Discreet, Compact, Simple Appearance:**
 - Easy to use whenever you need, wherever you are.

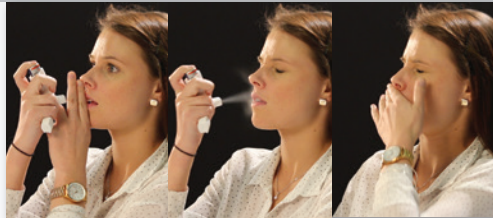


Without InFloCone

With InFloCone

*Pittsburgh Regional Health Initiative and Center for Healthcare Quality and Payment Reform © 2008-2011





No More Spray-In-The-Face



Use InFloCone Privately or . . .



While Active

Data Specifications

PROTOCOL: Aerosol Performance Testing of InFloCone and Commercial MDI - Ventolin HFA

RESULTS:

Aerosol Performance Comparison of InFloCone and Commercial MDI

	Particle Size (MMAD) (um)	Geometric Standard Deviation (ug/burst)	Total Dose Delivered by Device (ug/burst)	Total Respirable Dose (0.5-5 um) (ug/burst)	Coarse Particle Dose (>4.7 um) (ug/burst)	Fine Particle Dose (<4.7 um) (ug/burst)	Ultra-Fine Particle Dose (<1.0 um) (ug/burst)
InFloCone with Ventolin HFA							
1	2.0	2.2	67.4	43.4	23.9	43.4	9.5
2	1.9	2.1	70.0	44.9	24.1	45.9	9.7
3	1.7	2.1	71.7	47.8	21.2	50.5	13.6
Mean	1.87	2.14	69.7	45.4	23.1	46.6	10.9
Std Dev	0.15	0.05	2.2	2.2	1.6	3.6	2.3
Commercial MDI Ventolin HFA							
1	1.9	3.2	104.7	39.4	58.4	46.4	17.4
2	1.7	2.5	102.9	46.9	51.8	51.1	18.0
3	1.8	3.3	103.8	40.2	57.1	46.6	17.5
Mean	1.80	2.99	103.8	42.2	55.7	48.0	17.6
Std Dev	0.10	0.40	0.9	4.1	3.5	2.7	0.3
Statistical Analysis							
Mean D	0.07	0.85	34.1	3.2	32.7	1.4	6.7
T Stat.	0.63	3.62	25.02	1.18	14.58	0.56	5.00
T (p=0.05)	2.78	2.78	2.78	2.78	2.78	2.78	2.78
Sig ?	NO	YES	YES	NO	YES	NO	YES

Table 1 showing the performance of the InFloCone with Ventolin HFA as compared to the Ventolin HFA commercial MDI by itself. The statistical analysis shows there was no measurable difference in the two for particle size, respirable dose and fine particle dose. *Clinical Data: Piper Medical, Carmichael, CA*

Ordering Information

Order #	Description	Quantity
1357050	InFloCone in polybag w/instructions for use	50/box

Disposal/Cleaning

The InFloCone should be disposed of with the exhausted MDI it is being used with. While in use it can be cleaned with warm water and soap and air dried.

Distributed by:



PO Box 6024 / Granbury, TX 76049
 1.800.848.8923 / 817.326.6357
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www.alliancetekmedical.com

pMDI Guidance System Mouthpiece



Data Specifications

PROTOCOL: Aerosol Performance of the QVAR MDI in Various Configurations including use with the InFloCone and the AeroChamber Plus Z Stat

RESULTS:

Aerosol Performance

	Particle Size (MMAD)	Geometric Standard Deviation	Total Dose Delivered by Device	Total Respirable Dose (0.5-5 µm)	Coarse Particle Dose (>4.7 µm)	Fine Particle Dose (<4.7 µm)	Ultra-Fine Particle Fraction (<1.0 µm) as Percent of Valve Label
Configuration 1: MDI alone, aligned and sealed to throat inlet							
1	0.6	3.8	33.3	12.9	10.0	23.3	15.9
2	0.5	3.6	32.4	10.1	10.8	21.6	16.0
3	0.5	3.3	32.7	10.3	11.2	21.5	16.9
Mean	0.50	3.58	32.8	11.1	10.7	22.1	16.2
Std Dev	0.05	0.24	0.4	1.6	0.6	1.0	0.6
Configuration 2: MDI alone, ten degrees off angle and sealed to throat inlet							
1	0.6	2.9	31.6	11.4	8.7	22.9	16.8
2	0.6	3.6	35.5	12.1	11.2	24.2	17.5
3	0.5	3.0	35.3	10.5	13.4	21.9	16.8
Mean	0.53	3.18	34.1	11.4	11.1	23.0	17.0
Std Dev	0.03	0.40	2.2	0.8	2.3	1.2	0.4
Configuration 3: MDI alone, aligned and spaced two inches away throat inlet							
1	0.4	3.8	15.3	4.9	3.8	11.5	9.2
2	0.4	3.8	12.9	4.6	1.5	11.4	9.2
3	0.3	4.7	12.9	4.4	1.3	11.6	9.6
Mean	0.37	4.06	13.7	4.6	2.2	11.5	9.3
Std Dev	0.06	0.53	1.4	0.2	1.4	0.1	0.2
Configuration 4: MDI used with InFloCone							
1	0.6	2.8	27.6	12.3	6.0	21.6	15.4
2	0.5	3.6	26.3	9.9	5.6	20.8	15.1
3	0.4	3.8	24.7	7.9	6.6	18.1	14.2
Mean	0.50	3.39	26.2	10.0	6.1	20.2	14.9
Std Dev	0.10	0.49	1.4	2.2	0.5	1.8	0.6
Configuration 5: MDI used with Aerochamber							
1	0.5	2.7	29.5	12.5	2.1	27.4	22.4
2	0.5	2.8	28.8	13.4	1.1	27.7	21.9
3	0.4	2.5	25.9	9.1	3.3	22.6	19.4
Mean	0.45	2.66	28.1	11.7	2.2	25.9	21.2
Std Dev	0.05	0.15	2.0	2.3	1.1	2.9	1.6

Table showing the aerosol performance of the five configurations. All doses in micrograms.

Clinical Data: Piper Medical, Carmichael, CA

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ENHANCE DELIVERY

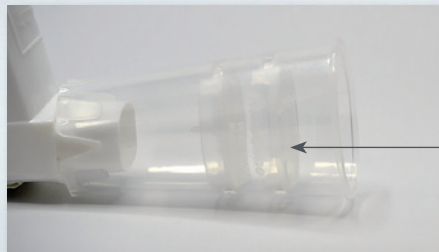
pMDI Guidance System Mouthpiece



Alliance

TECH MEDICAL

The Technically Advanced *InFloCone™ V*



Valve



Vertical Preference



Horizontal Preference



InFloCone V (IFCV) disposable mouthpiece **with valve** is designed to prevent blow-back and provide the user with consistent and efficient delivery when inhaling pressurized, metered dose medications.

Straight-Forward Guidance

Studies show that as many as 79% of patients could be misusing their inhalers.*

The IFCV will help to avoid the random mishaps and effects of medicine spray into your face. It will also allow the momentum of high speed propelled aerosol to slow as you inhale while adding a degree of repeatability to the delivery of each dose.

• **Straight-Forward Delivery Guidance:**

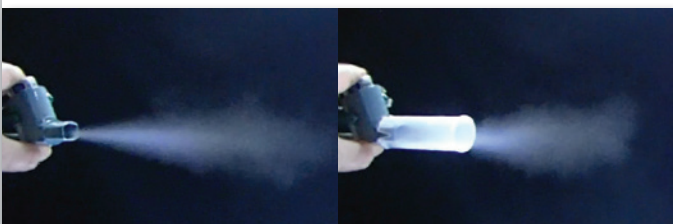
- Aids coordination so user can concentrate on inhalation technique.
- IFCV allows for propelled medication to be received more slowly.

• **Economical:**

- No need to replace canister or boot after each use.
- Far less expensive than a Holding Chamber.

• **Helps to Eliminate Cross-Contamination:**

- Innovative design helps to prevent blow-back during inhalation.

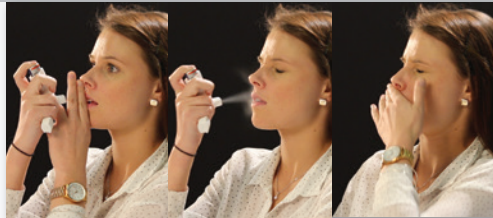


Without InFloCone V

With InFloCone V

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No More Spray-In-The-Face



Use InFloCone V Privately or . . . While Active



Data Specifications

PROTOCOL: Aerosol Performance of InFloCone with Valve IFCV While Used with QVAR MDI

RESULTS:

Aerosol Performance

	Particle Size (MMAD) (microns)	Geometric Standard Deviation	Total Dose Delivered by Device (ug)	Total Respirable Dose (ug 0.5-5 um)	Coarse Particle Dose (ug > 4.7 um)	Fine Particle Dose (ug > 4.7 um)	Ultra-Fine Particle Dose (ug > <1.0 um)
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Configuration 4: MDI used with InFloCone from Piper Protocol 15-0098

1	0.60	2.83	27.6	12.3	6.0	21.6	15.4
2	0.50	3.60	26.3	9.9	5.6	20.8	15.1
3	0.40	3.75	24.7	7.9	6.6	18.1	14.2
Mean	0.50	3.39	26.2	10.0	6.1	20.2	14.9
Std Dev	0.10	0.49	1.4	2.2	0.5	1.8	0.6

InFloCone with Valve

1	0.42	2.86	28.0	10.8	2.5	25.6	20.9
2	0.42	2.62	29.5	11.3	2.2	27.3	22.3
3	0.40	2.75	27.4	10.4	2.3	25.1	20.5
Mean	0.41	2.74	28.3	10.8	2.3	26.0	21.3
Std Dev	0.01	0.12	1.1	0.5	0.2	1.2	1.0

Statistical Analysis

Mean D	0.09	0.65	2.1	0.8	3.8	5.8	6.3
T Stat.	1.49	2.23	1.98	0.60	12.59	4.69	9.54
T (p=0.05)	2.78	2.78	2.78	2.78	2.78	2.78	2.78
Sig ?	NO	NO	NO	NO	YES	YES	YES

Table 1 showing the aerosol performance of the InFloCone without valve as measured in Piper Protocol 15-0098 and the InFloCone with Valve as measured in this protocol. The statistical analysis shows that the measurable differences for Coarse Particle Dose, Fine Particle Dose and Ultra-Fine Particle Dose were all statistically significant at a confidence level of 95%.
Clinical Data: Piper Medical, Carmichael, CA

Ordering Information

Order #	Description	Quantity
1459050	InFloCone V in polybag w/instructions for use	50/box

Disposal/Cleaning

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