Membrane Technologies

AseptiCap® Nano

Hydrophilic Polyethersulfone (PES)

Membrane Capsule Filters

Data Sheet

Sterilizing filtration of nano particle drug delivery systems, is a challenge. The nano particle size range is from 140nm to 160nm which tend to get retained by the 0.2µm (200nm) sterilizing membrane filter, Thereby drastically effecting the downstream yield.

mdi *AseptiCap® Nano* Capsule filters are ready to use, disposable, highly retentive filtration devices specially designed for difficult to filter nano particles based drug formulations. These filters house specifically designed asymmetric PES membrane which allows high yield (> 90%) while assuring a sterile downstream.

These filter devices are validated to meet compendia and regulatory requirements and are well characterized. They meet key process requirements such as high retention efficiency, extremely low extractables, high throughputs, wide chemical compatibility and other important characteristics.

AseptiCap® Nano

PES Membrane Capsule Filters

Datasheet

AseptiCap® Nano capsule filters use **mdi** PES membrane in Polypropylene housing. No adhesives or glue are used in the manufacturing process and all bonding is done by heat welding.

The products are deeply validated for use in sterilizing filtration of nano particle based drug delivery system. *AseptiCap® Nano* capsule filters are manufactured in class 10,000 clean rooms and ISO 9001 certified facilities. Packaging is done in double polybags for convenience of taking *AseptiCap®* Nano in clean areas for making disposable assemblies for subsequent sterilization.

Key Features

- Absolute retention
- 100% integrity tested
- Low hold up volume for minimal filtration losses
- Very low extractables
- High flow rates
- Bioburden maintained below 1000 cfu/device
- Endotoxin level certified to be <0.25 EU/ml
- Widest range of end connections
- Products available for total scalability
- Total traceability through unique serial number for each filter
- Individual certificate of quality for each device

Applications

- Sterile filtration of nano particle based drug formulations

Validation Services

The regulatory requirements emphasize on the need to validate the efficacy of the 'Sterilizing Filter' with drug product under simulated worst-case conditions of use.

mdi provides validation services supported by customized validation protocols and world class test facilities to assist you in filter validations with your specific drug product.

Quality Assurance

mdi quality management system emphasizes on quality by design rather by end product testing. Robust processes are developed for product manufacturing and are continuously monitored to ensure that the products meet their predetermined specifications and lot to lot reproducibility is ensured.

Certificate of Quality

Each capsule filter is accompanied by individual certificate of quality to ensure traceable documentation at user's end.

It certifies the product compliance to various regulatory as well as user requirements.

Validated for Microbial Retention

Integrity test data have been correlated to actual microbial retention with *B.diminuta* (ATCC 19146) as per ASTM F838 to establish acceptable integrity test values.

Samples from each lot are subjected to microbial challenge test before final lot release.

100% Integrity Tested

Each *AseptiCap® Nano* is tested for integrity to comply with validated Acceptable Integrity Test Specifications.

Flow Rate

Each lot is tested for clean water flow rates to ensure that flow rates are within the specifications.

Pressure, Temperature Endurance

AseptiCap® Nano filters are validated to endure high operating pressure and temperature conditions which may be encountered during use.

These filters are also validated for high burst pressure to ensure user safety in case of inadvertent pressure build-up.

Extractables

Extractables/leachables from *AseptiCap® Nano* filters will add on and may impact the impurity profile of the desired product.

AseptiCap® Nano filters are validated to exhibit low extractables under harsh extraction conditions.

Bioburden Testing

Device bioburden is tested as per ISO 117 37-1 and assured to be <1000 cfu/device.

Endotoxin Testing

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>

Total Traceability

AseptiCap® Nano capsule filters come with completely traceable lot numbers and unique identification number to facilitate easy and fast retrieval of manufacturing and quality control data associated with each filter.

These unique lot and identification numbers are laser etched on each filter device and also printed on the labels of the box in which individual filter is packed.

Packaging Integrity

AseptiCap® Nano capsule filters are fitted with vent caps and are packed in bags to ensure package integrity during transit as well as to prevent particulate contamination while transferring to clean room assembly or process areas.

Other Regulatory Compliance

- Complies with USFDA 21 CFR 210.3(b)(6) for fiber release
- Complies with USFDA 21 CFR 177.1520 for fractional dissolution
- Materials of construction tested for toxicity as per Biological Reactivity Tests, In-vivo, USP <88> for class VI Plastics

Easy Connect

Datasheet

Widest Range of End Connections

Aseptic processes involve filtration of high value fluids. Making high quality, reliable, flexible and functionally convenient connectivity with filters is of utmost value to the process owners.

mdi *AseptiCap® Nano* filters offer a wide range of reliable end connections for functional convenience and customized connectivity.

Validated for Performance

These end connections are manufactured with tight dimension tolerance and are validated for strength and connection integrity under extreme use conditions as well as for their ability to withstand prevalent sterilization method inluding autoclaving.

½" HB

½" Single Stepped Hose Barb

1/4" MNPT

¼" SHB

Quick Connector

Male Luer Slip

3/8" Hose Barb

Female Luer Lock

1½" Sanitary Flange

¾" Sanitary Flange

½" MNPT

1" Hose Barb

Variety of end connections

Customized Connectivity

mdi *AseptiCap® Nano* filters are available in a wide range of end connections and are also customized to offer different inlet-outlet combinations to meet the unique connectivity needs in pharmaceutical processes.

1½" Sanitary Flange to ½"Barb Hose

1½" Sanitary Flange to ¾" Sanitary Flange

***AseptiCap®* with HighSecurity ½" hose barb connection**

Linear Upscaling from R&D to Production Process

Datasheet

mdi offers a wide range of *AseptiCap® Nano* filters to provide linear scale up from lab scale to production process. While scaling up the process, the appropriate size filter can be selected by increasing the effective filtration area of filter proportionate to the process fluid volumes.

All Materials of construction as well as manufacturing process are identical for all filter devices starting from 5 cm^2 to 10000cm^2 hence process scaling can be facilitated without triggering additional validation studies for given process conditions. **mdi** provides complete documentation for each of the *AseptiCap® Nano* filters there by reducing the additional validation cost and time.

AseptiCap® Nano
25 mm, 5cm^2

AseptiCap® Nano
50 mm, 20cm^2

AseptiCap® Nano
1", 150cm^2

AseptiCap® Nano
2", 400cm^2

AseptiCap® Nano
5", 800cm^2

AseptiCap® Nano
8", 1250cm^2

AseptiCap® Nano
10", 3500cm^2

AseptiCap® Nano
20", 7000cm^2

AseptiCap® Nano
30", 10000cm^2

Filter Devices	EFA* (Nominal)	Hold up Volume
AseptiCap® Nano 25 mm	5cm^2	< 50µl
AseptiCap® Nano 50 mm	20 cm^2	< 200µl
AseptiCap® Nano 1"	150cm^2	< 5ml
AseptiCap® Nano 2"	400cm^2	< 25ml
AseptiCap® Nano 5"	800cm^2	< 45ml
AseptiCap® Nano 8"	1250cm^2	< 60ml
AseptiCap® Nano 5"	1750cm^2	< 80ml
AseptiCap® Nano 10"	3500cm^2	< 150ml
AseptiCap® Nano 20"	7000cm^2	< 250ml
AseptiCap® Nano 30"	10000cm^2	< 350ml

***EFA: Effective Filtration Area**

Specifications

AseptiCap® Nano

Datasheet

Construction		
Membrane	Hydrophilic PES	
Plastic parts	Polypropylene	
Size		
Size	25mm	50mm
Effective Filtration Area (Nominal)	5 cm^2	20 cm^2
Operational Radius	15 mm	28 mm
Operational		
Max. Operating Temperature	55 °C	60 °C
Max. Differential Pressure	75 psi (5 Kg/cm^2) @ 25 °C	42 psi (3 Kg/cm^2) @ 30 °C
Sterilization By Autoclave	Autoclavable at 125 °C for 30minutes. Can not be in-line steam sterilized	
Assurance		
Toxicity	Passes Biological Reactivity Tests, In vivo, as per USP <88> for Class VI plastics	
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>	
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release	
TOC and Conductivity	Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after a 500ml flush	
Extractables with WFI	Passes NVR test as per USP <661>	
Indirect Food Additives	Comply with USFDA 21 CFR Part 177.1520	
Oxidizable Substances	Within limits as specified in USP <1231>	
Quality Management System	ISO-9001 Certified	
USFDA	DMF No. 015554	

Specifications

AseptiCap® Nano

Datasheet

Construction				
Membrane	Hydrophilic PES			
Plastic parts	Polypropylene			
Integrity Testing				
Air Diffusion Flows @20 psi	1″	2″	5″	8″
	≤ 0.5 ml/min	≤ 1.2 ml/min	≤ 2.5 ml/min	≤ 4 ml/min
Size				
Size	1″	2″	5″	8″
Effective Filtration Area (Nominal)	150cm^2	400cm^2	800cm^2	1250 cm^2
Operational Radius (with Vent/ Drain)	40 mm	65 mm	65 mm	65 mm
Vent and Drain	¼″ Hose Barb with Silicone "O" rings			
Operational				
Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm^2)			
Max. Differential Pressure	60 psi (4 Kg/cm^2) @ 30 °C			
Sterilization By Autoclave	Autoclavable at 125 °C for 30minutes. Can not be in-line steam sterilized			
Assurance				
Toxicity	Passes Biological Reactivity Tests, In vivo, as per USP <88> for Class VI plastics			
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>			
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release			
TOC and Conductivity	Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after a 3 liter flush			
Extractables with WFI	Passes NVR test as per USP <661>			
Indirect Food Additives	Comply with USFDA 21 CFR Part 177.1520			
Oxidizable Substances	Within limits as specified in USP <1231>			
Quality Management System	ISO-9001 Certified			
USFDA	DMF No. 015554			

Specifications

AseptiCap® Nano

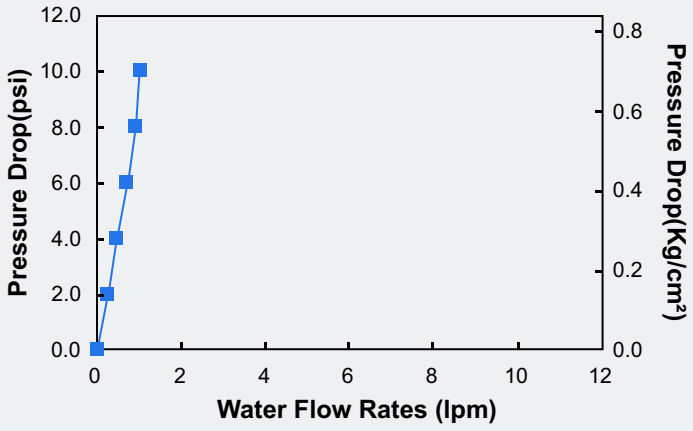
Datasheet

Construction				
Membrane	Hydrophilic PES			
Plastic parts	Polypropylene			
Integrity Testing				
Air Diffusion Flows @20 psi	5″	10″	20″	30″
	≤ 4.2 ml/min	≤ 8.4 ml/min	≤ 16.8 ml/min	≤ 25 ml/min
Size				
Size	5″	10″	20″	30″
Effective Filtration Area (Nominal)	1750cm^2	3500cm^2	7000cm^2	10000cm^2
Operational Radius (with Vent/ Drain)	80 mm	80 mm	80 mm	80 mm
Vent and Drain	¼″ Hose Barb with Silicone "O" rings			
Operational				
Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm^2)			
Max. Differential Pressure	60 psi (4 Kg/cm^2) @ 30 °C			
Sterilization By Autoclave	Autoclavable at 125 °C for 30minutes. Can not be in-line steam sterilized			
Assurance				
Toxicity	Passes Biological Reactivity Tests, In vivo, as per USP <88> for Class VI plastics			
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>			
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release			
TOC and Conductivity	Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after a 10 liter flush for 5″ capsule filters and 20 liter flush for 10″ capsule filters			
Extractables with WFI	Passes NVR test as per USP <661>			
Indirect Food Additives	Comply with USFDA 21 CFR Part 177.1520			
Oxidizable Substances	Within limits as specified in USP <1231>			
Quality Management System	ISO-9001 Certified			
USFDA	DMF No. 015554			

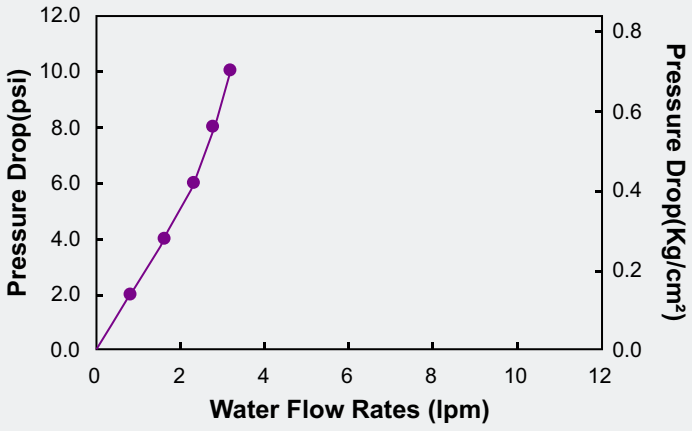
Typical Water Flow Rates Small Capsule Filters

Datasheet

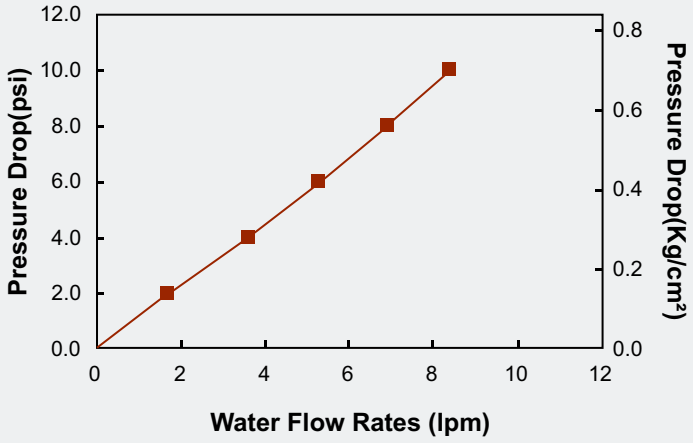
AseptiCap® Nano, 1" Capsule Filters



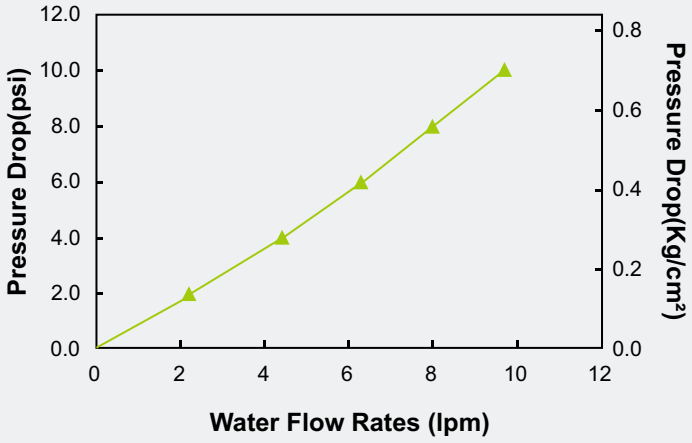
AseptiCap® Nano, 2" Capsule Filters

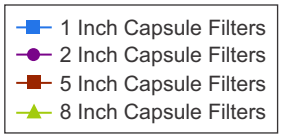


AseptiCap® Nano, 5" Capsule Filters



AseptiCap® Nano, 8" Capsule Filters



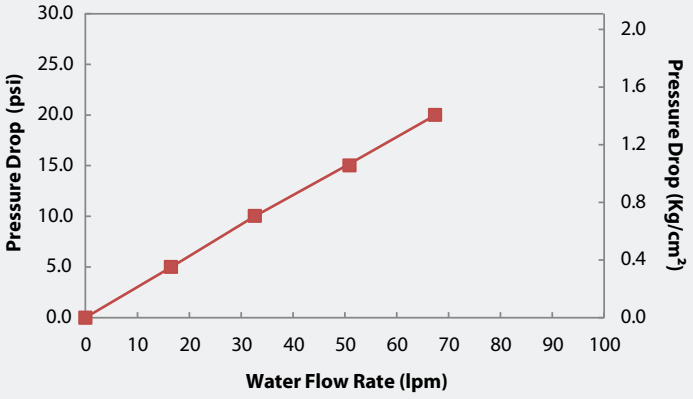


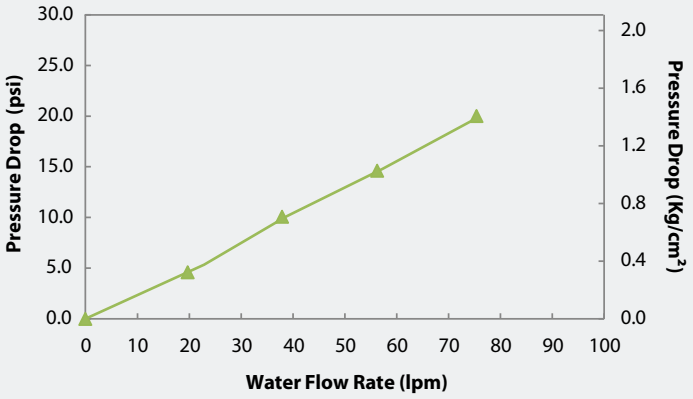
End Connection Type- D: ½" Hose Barb

Typical Water Flow Rates
Large Capsule Filters

Datasheet

AseptiCap® Nano, 10" Capsule Filters





10 Inch Capsule Filters, QQ Connection
10 Inch Capsule Filters, EE Connection

End Connection Type:

E : 1½" Sanitary Flange
Q : Single Step ½" Hose Barb

Ordering Information

AseptiCap® Nano 25mm PES Membrane Capsule filter

Type		Size		Retention Rating	Inlet/Outlet		X	X	Sterility		Pack Size	
	Code		Code	S7		Code				Code		Code
AseptiCap® Nano	IKNX	25mm	06		Female Luer Lock	M			Non Sterile	1	100	04
					Male Luer Slip	N						
					⅛" Hose Barb	H						
					¼" Hose Barb	B						

Example:

IKNX	06	S7	MN	X	X	1	04

AseptiCap® Nano 50mm PES Membrane Capsule filter

Type		Size		Retention Rating	Inlet/Outlet		X	X	Sterility		Pack Size	
	Code		Code	S7		Code				Code		Code
AseptiCap® Nano (without vent)	IKNX	50mm	10		¼" SHB	B			Non Sterile	1	12	08
AseptiCap® Nano (with vent)	VKNX				¾" Sanitary Flange	S						
					Female Luer Lock	M						
					¼" Single Step Hose Barb	A						

Example:

VKNX	10	S7	BB	X	X	1	08

Inlet/Outlet Connections Available

Inlet/Outlet	25mm	50mm	
		with Vent	without Vent
¼" - ¾" Stepped Hose Barb	X	√	X
¾" Sanitary Flange	X	√	X
Female Luer Lock	Inlet Only	X	√
Male Luer Slip	Outlet Only	X	X
⅛" Hose Barb	√	X	X
Male Luer Lock	Outlet Only	X	X
¼" Hose Barb	√	X	X
¼" Single Step Hose Barb	X	X	√

Dimension (Length) (in mm)

Inlet/ Outlet	25mm	50mm
¼" - ⅜" Stepped Hose Barb I/O	-	79
¼" Hose Barb I/O	38	-
¼" Single Step Hose Barb I/O	-	62
¾" Sanitary Flange I/O	-	51
Female Luer Lock Inlet/ Male Luer Slip Outlet	23	-
⅛" Hose Barb I/O	36	-

Operational Radius	15	28

Ordering Information

AseptiCap® Nano PES Membrane Small Capsule filter

Type		Size		Retention Rating	Inlet/Outlet		X	X	Sterility		Pack Size	
	Code		Code	S7		Code				Code		Code
AseptiCap® Nano	DKNX	1″	51		¼″ SHB	A			Non Sterile	1	1	01
		2″	52		½″ Hose Barb	D						
		5″	53		1½″ Sanitary Flange	E						
		8″	57		¾″ Sanitary Flange	S						
					Quick Connector	J						
					½″ Single Step Hose Barb	Q						
					Female Luer Lock	U						
					Male Luer Slip	W						
					3/16″ Hose Barb	N						
					3/8″ Hose Barb	I						
					¼″ Single Step Hose Barb	R						

Example:

DKNX	57	S7	DD	X	X	1	01

Note: Inlet/Outlet Connections available with different Sizes/Length as follows:

Inlet/Outlet	Size/Length			
	1″	2″	5″	8″
¼″ Stepped Hose Barb	√	√	√	√
½″ Single Step Hose Barb	X	√	√	√
½″Hose Barb	√	√	√	√
1½″ Sanitary Flange	√	√	√	√
¾″ Sanitary Flange	√	√	√	√
Quick Connector	√	√	√	√
Female Luer Lock	√	√	√	√
Male Luer Slip	Outlet Only	X	X	X
3/16″ Hose Barb	√	√	Outlet Only	X
3/8″ Hose Barb	√	√	√	√
¼″ Single Step Hose Barb	√	√	√	√

Dimensions (in mm)	Small Capsule Filters			
End Connections	**1″**	**2″**	**5″**	**8″**
¼″ SHB I/O	94	122	172	223
¾″ Sanitary Flange Inlet I/O	85	104	155	206
Quick Connector	100	113	164	218
1½″ Sanitary Flange I/O	92	112	164	216
½″ Hose Barb I/O	90	112	162	214
½″ Single Step Hose Barb I/O	-	115	165	218
1½″ Sanitary Flange Inlet ½″ Single Step Hose Barb Outlet	-	112	165	216
3/8″ Hose Barb I/O	-	115	167	217
¼″ Single Step Hose Barb I/O	90	106	160	212
Operational Radius	40	65	65	65

Ordering Information

Datasheet

AseptiCap® Nano PES Membrane Large Capsule filter

Type	
	Code
AseptiCap® Nano	LKNX

Size	
	Code
5″	53
10″	54
20″	55
30″	56

Retention Rating
S7

Inlet/Outlet	
	Code
1½″ Sanitary Flange	E
Single Step ½″ Hose Barb	Q
3/8″ Hose Barb	I
1″ Hose Barb	Z
3/4″ Sanitary Flange	S

X

Inline/ T-line	
	Code
In-line	X
T-line	T

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

LKNX	57	S7	EE	X	X	1	01

Note: Inlet/Outlet Connections available with different Sizes/Length as follows:

Inlet/Outlet	Inline				T-Line		
	5″	10″	20″	30″	10″	20″	30″
½″ Single Step Hose Barb	√	√	√	√	X	X	X
1½″ Sanitary Flange	√	√	√	√	√	√	√
¾″ Sanitary Flange	√	√	X	X	X	X	X
⅜″ Hose Barb	√	√	√	√	X	X	X
1″ Hose Barb	X	√	√	√	X	X	X

Dimensions (in mm)	Inline Capsule Filters				T-line Capsule Filters		
End Connections	**5″**	**10″**	**20″**	**30″**	**10″**	**20″**	**30″**
1½″ Sanitary Flange I/O	205	330	600	855	340	580	840
¾″ Sanitary Flange I/O	214	335	x	x	x	x	x
½″ Single Step Hose Barb I/O	218	336	630	890	x	x	x
1½″ Sanitary Flange Inlet ½″ Hose Barb Outlet	212	334	620	870	x	x	x
⅜″ Hose Barb I/O	211	332	634	885	x	x	x
1″ Hose Barb I/O	x	405	635	895	x	x	x
Operational Radius	80	80	80	80	80	80	80

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