

mdi AseptiFit™ Fittings are single use polypropylene components used in customized single use assemblies. A wide range of gamma stable fittings such as cross connections, T connections, Y connections, reducers and funnel adaptors are available to support various plumbing requirements within these customized single use systems.

Specifications

Biosafety

Passes Biological Reactivity test, In-Vivo, as per USP<88> for Class VI plastics.

Sterilization

Gamma Sterilizable upto 50 kGy
Autoclavable for One cycle @125°C for 30 minutes

Sterility

The gamma sterilization process has been validated as per ISO 11137 to ensure a sterility assurance level (SAL) of 10⁻⁶.

Bioburden Testing

Bioburden level is < 1000 cfu/device as per ISO 11737-1:2018.

Endotoxin Testing

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

Particle Release

Complies with USP <788> test for particulate matter in injections.

Non Animal Origin

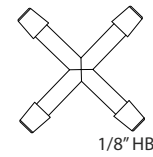
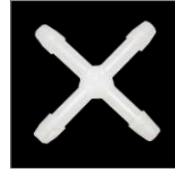
The materials used for manufacture **mdi AseptiFit™** fittings do not contain substance of animal origin as per EMEA/410/01 Rev.03.

Shelf Life

5 years before gamma sterilization
2 years after gamma sterilization

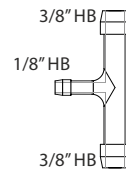
Tubing Connections

Cross Connection



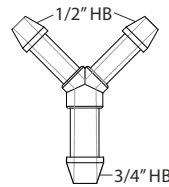
Size
1/8" HB (5mm nipple)

T Connection



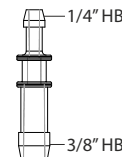
Sizes
3 X 1/8" HB
3 X 3/8" HB
2 x 3/8" and 1 x 1/8" HB

Y Connection



Sizes
1/8" HB (5mm nipple Y)
1/4" HB
3/32" HB
2 x 3/32" and 1 x 1/8" HB
2 x 1/2" x 1 x 3/4" HB

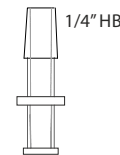
Reducers



Sizes
1/4" to 1/8" HB
3/8" to 1/4" HB
1/2" to 1/4" HB
1/2" to 3/8" HB
3/4" to 1/2" HB
1" to 1/2" HB
3/8" HB to Female Luer lock
1/8" HB to Female Luer lock
Male luer slip nipple with 1/8" HB

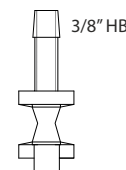
Plugs

Press in Plugs



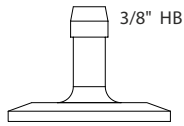
Sizes
1/8" Hose Barb
1/4" Hose Barb
3/8" Hose Barb
1/2" Hose Barb

Baxa Spike

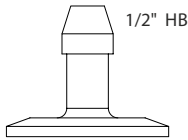


with 3/8" Hose Barb

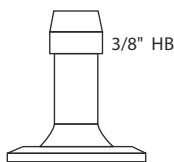
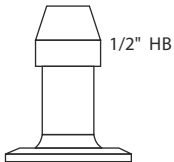
1/2" Sanitary Flange with Hose Barb Connection



Sizes
1/4" Hose Barb
3/8" Hose Barb
1/2" Hose Barb
3/4" Hose Barb
1" Hose Barb

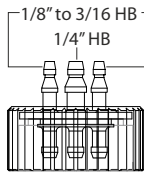


3/4" Sanitary Flange with Hose Barb Connection



Sizes
1/4" Hose Barb
3/8" Hose Barb
1/2" Hose Barb
3/4" Hose Barb

Bottle Covers



Sizes
2 x 1/8"-1/8" HB and 1 x 1/4"-1/8" HB for 45mm Bottle Cover
2 x 1/8"-1/8" to 3/16"-1/8" HB for 33mm Bottle Cover
1 x 1/8"-1/8" HB and 1 x 1/4"-1/8" HB for 38mm Bottle Cover
2 x 1/8"-1/8" HB and 1 x 1/4"-1/4" HB for 53mm Bottle Cover
1 x 1/4"-1/8" HB and 3 x 1/4"-1/4" HB for 83mm Bottle Cover

Quality Management System

mdi AseptiFit™ Fittings are well designed products with in-built quality assurance. ISO-9001:2015 Certified Quality Management System, careful selection of raw materials, validated production processes and testing procedures based on international standards and guidelines such as CFR, PDA, and ASTM, ensures manufacture of consistently high quality fittings.

Manufacturing Facilities

mdi AseptiFit™ Fittings are manufactured in clean rooms certified by external agencies and monitored in-house for viable and non viable particles. Employee hygiene, change rooms, gowning and de-gowning procedures and continuous monitoring of the areas is an essential part of these facilities. These facilities have been designed for unidirectional work flow with appropriate change rooms for personnel and pass boxes for material movement.