



IV Extension Sets September 2024

About DirectMed

DirectMed, Inc, was founded in 1997 as a source for a wide selection of high-quality components for medical devices. Since then, we have expanded our capabilities to offer full customization on any of our standard OEM components. Since 2018, we have been offering a full line of private-label devices for fluid management.

Our excellence in customer service, competitive pricing, and timely delivery are key to our continuing mission to provide the best possible quality on time, every time.

We maintain a wide stock of components and work with our manufacturing partners from around the world to source every possible option, OEM or fully custom-made. Our team will liaise with your product engineers from concept to prototypes to full production. We aim to minimize risk and add efficiency to the supply chain model from idea to market with our customized solutions and logistics support.

Whether you are seeking a source for OEM components or a complete, ready-to-use device, we can help you in the following key areas:

Supply Chain

We work with our contract manufacturing partners to optimize supply chain management. This ensures we can take the device from start to market in one comprehensive and efficient project path.

Fulfillment

Our manufacturing partners' facilities create and deliver millions of units every year. Each unit is tailored exactly to customer specifications including the product itself, packaging, and delivery schedule.

Proactive Troubleshooting

Our team's 25+ years in design and development allow us to identify hurdles associated with your project <u>in advance</u>. Predicting upcoming issues with production before they happen prevents delays in getting your product to market.

Partnership

We believe that being your supplier means being a part of your team. This also allows you to focus on what you do well and leave the manufacturing oversight to an experienced partner like us who has relationships with our key vendors developed over 25 years. Our manufacturing partners' facilities are ISO 13485 and ISO 9001 certified. Our products can be sterilized using a number of different methods.

About DirectMed

DirectMed Location

DirectMed, Inc. global headquarters is located at:

98 Pratt Oval, Glen Cove, NY 11542 USA

The facility is home to our extensive warehouse facility and the core of our logistics, sales, and customer service teams. If you need assistance in your native language, you may contact us in English, French, German, Spanish, or Italian.

sales@directmed.com +1 (516) 656-3377

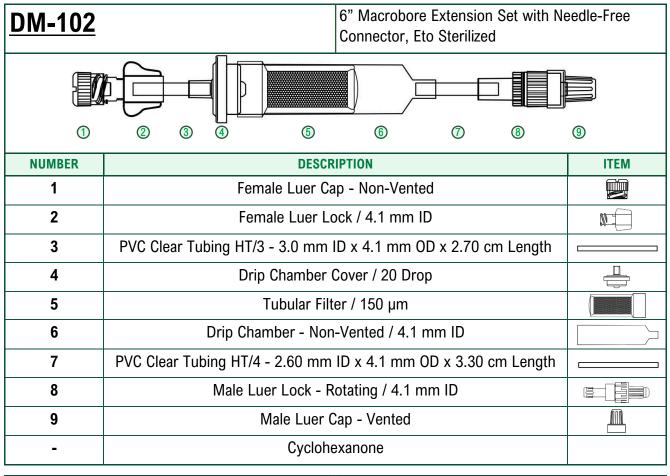


Available Parts - Build Your Custom Set

Cap for Male Luer	Cap for Female Luer	T Connector with Rotating MLL	Y Connector - Bifurcated	Y Connector - Trifurcated
Check Valve - Inline	Check Valve with MLL	Check Valve - MLL to FLL	Drip Chamber	Drip Chamber Cover
Filter - Inline IV	Filter - Tubular	Flow Regulator	Neutral Needleless Injection Site	Neutral Needleless Y Injection Site
Y Injection Site - Dual Access	Y Injection Site - Standard	Luer - Female	Female Luer Lock	Male Luer Lock
Rotating Male Luer Lock	Clamp - Pinch	Clamp - Roller	Clamp - Slide	Clamp - Open Slide
	BB			
IV Spike - Vented	Stopcock - 3 Way	Stopcock - 4 Way	Syringe	Tubing

Extension Sets

Fully Customizable



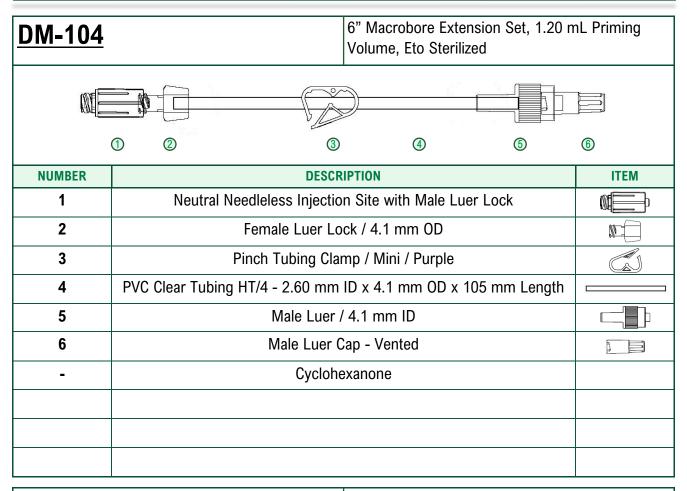
DM-103

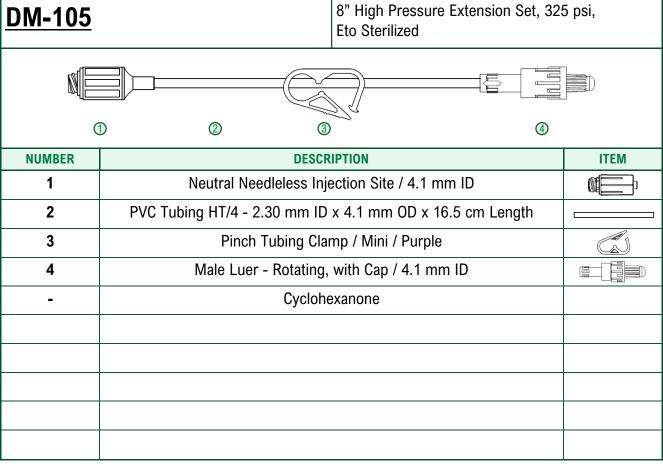
6" Minibore Extension Set with Needle-Free Connector, 0.60mL Priming Volume, Eto Sterilized



NUMBER	DESCRIPTION	ITEM
1	Neutral Needleless Injection Site with Male Luer Lock	
2	Female Luer / 2.5 mm ID	
3	PVC Tubing HT/4 - 0.50 mm ID x 2.50 mm OD x 15 cm Length	
4	Slide Tubing Clamp / Mini / White	
5	Male Luer - Rotating, with Slide-Off Hub and Cap / 2.5 mm ID	
-	Cyclohexanone	
-		

Extension Sets

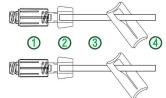


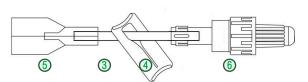


DM-106

Extension Sets

5" Minibore Bi-Fuse Extension Set, High-Pressure, 0.60 mL Priming Volume, Eto Sterilized

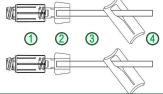




NUMBER	DESCRIPTION	ITEM
1	Neutral Needleless Injection Site with Male Luer Lock	
2	Female Luer / 2.1 mm ID	
3	PVC Tubing HT/4 - 0.50 mm ID x 2.50 mm OD x 4 cm Length	
4	Slide Tubing Clamp / Mini / White	
5	Y Connector to Male Luer Slip / 2.4 mm ID	
6	Male Luer - Rotating, with Slide-Off Hub and Cap / 2.5 mm ID	
-	Cyclohexanone	

DM-107

5" Minibore Bi-Fuse Extension Set, High-Pressure, 0.65 mL Priming Volume, Eto Sterilized

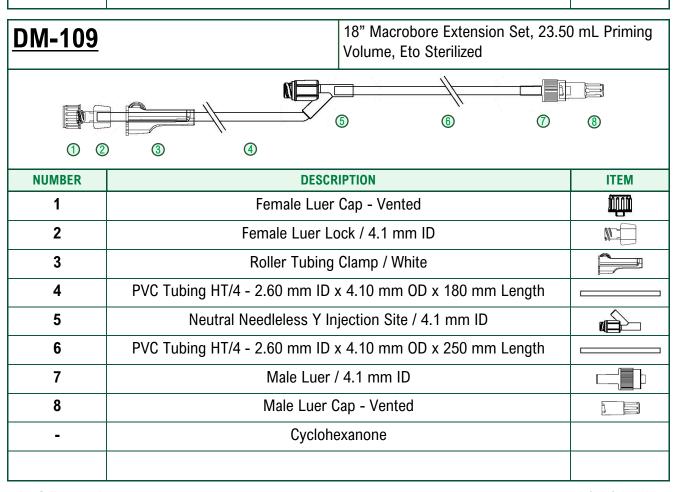


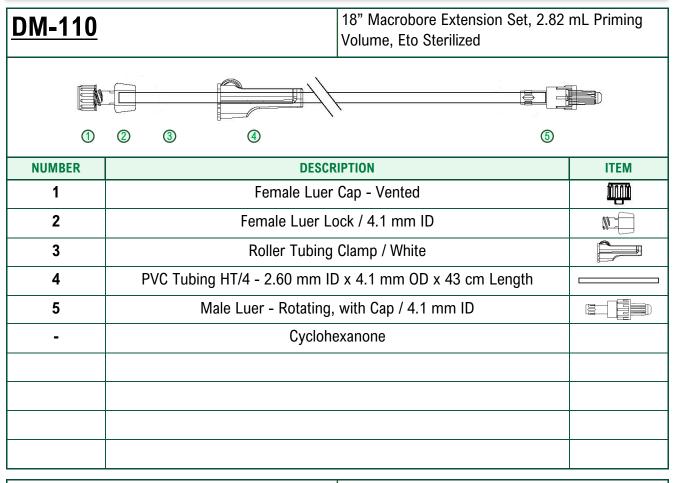


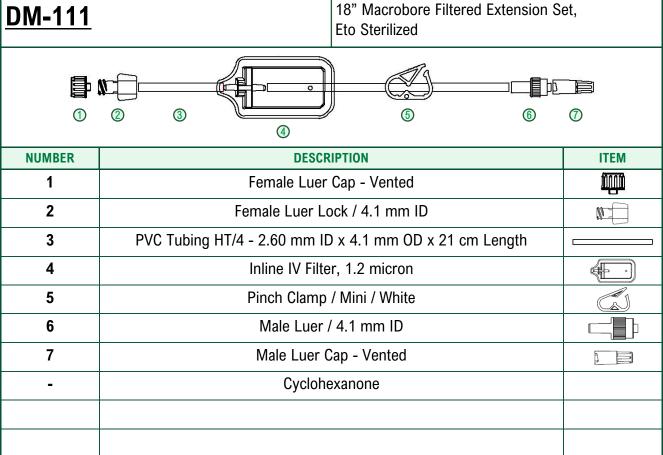
NUMBER	DESCRIPTION	ITEM
1	Neutral Needleless Injection Site with Male Luer Lock	
2	Female Luer / 2.1 mm ID	
3	PVC Tubing HT/4 - 0.50 mm ID x 2.50 mm OD x 4 cm Length	
4	Slide Tubing Clamp / Mini / White	
5	Y Connector to Male Luer Slip / 2.4 mm ID	
6	Male Luer - Rotating, with Slide-Off Hub and Cap / 2.5 mm ID	
-	Cyclohexanone	

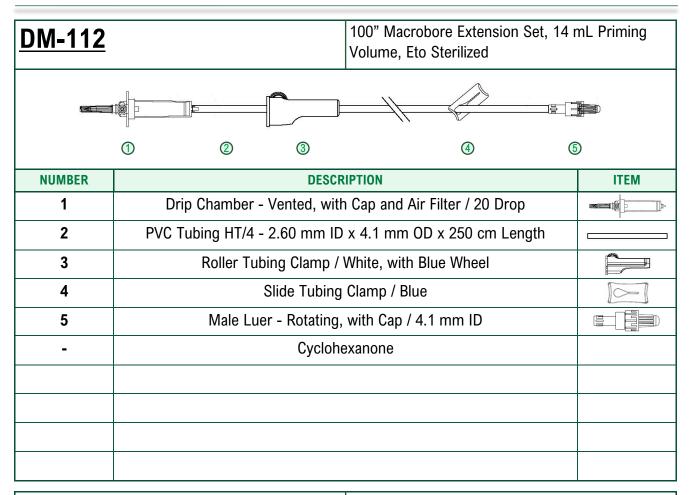
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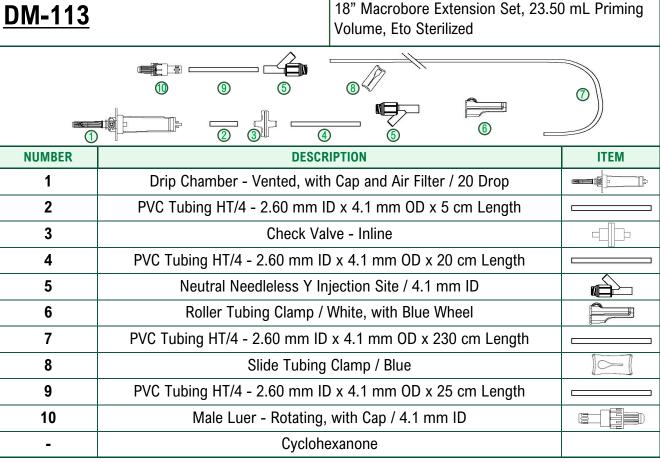
5" Minibore Tri-Fuse Extension Set, High-**DM-108** Pressure, 0.75 mL Priming Volume, Eto Sterilized 1 2 3 3 **DESCRIPTION NUMBER ITEM** 1 Neutral Needleless Injection Site with Male Luer Lock Female Luer / 2.1 mm ID 2 3 PVC Tubing HT/4 - 0.5 mm ID x 2.50 mm OD x 4 cm Length 4 Slide Tubing Clamp / White Y Connector - Triple / 2.1 mm ID 5 Male Luer - Rotating, with Slide-Off Hub and Cap / 2.5 mm ID 6 Cyclohexanone







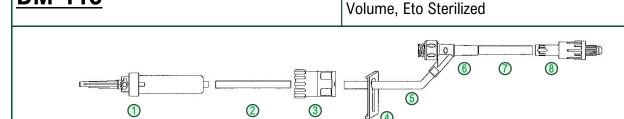




60" Macrobore Extension Set, 8.50 mL Priming **DM-114** Volume, Eto Sterilized 4 3 **NUMBER DESCRIPTION ITEM** Female Luer Cap - Vented 2 Female Luer / 4.1 mm ID 3 Slide Tubing Clamp / White PVC Tubing HT/4 - 2.60 mm ID x 4.1 mm OD x 150 cm Length 4 Male Luer - Rotating, with Cap / 4.1 mm ID 5 Cyclohexanone

Extension Sets

DM-115



90" Macrobore Extension Set, 18 mL Priming

NUMBER	DESCRIPTION	ITEM
1	Drip Chamber - Vented, with Cap and Air Filter / 20 Drop	
2	PVC Tubing HT/4 - 2.60 mm ID x 4.10 mm OD x 55 cm	
3	Flow Regulator	
4	Slide Tubing Clamp / Blue	
5	PVC Tubing HT/4 - 2.60 mm ID x 4.10 mm OD x 165 cm	
6	Y Injection Site	
7	PVC Tubing HT/4 - 2.60 mm ID x 4.10 mm OD x 15 cm	
8	Male Luer - Rotating, with Cap / 4.1 mm ID	
-	Cyclohexanone	

8.54 mm 4.06 mm

ID:

0.10" / 2.54 mm

OD:

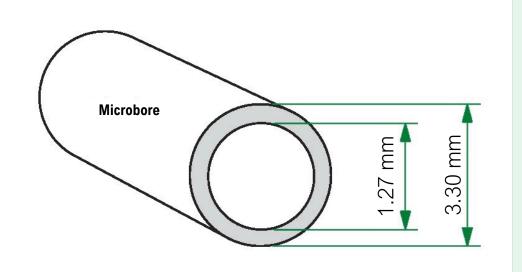
0.16" / 4.06 mm

Tolerance:

± 0.05 mm

Durometer:

Shore A 75 (±3 A)



ID:

0.05" / 1.27 mm

OD:

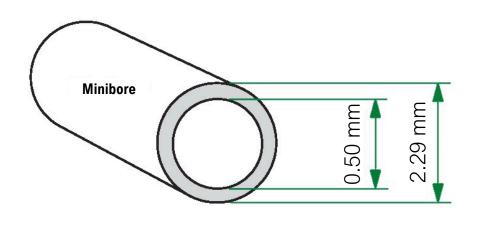
0.13" / 3.30 mm

Tolerance:

± 0.03 mm

Durometer:

TBD



ID:

0.02" / 0.50 mm

OD:

0.09" / 2.29 mm

Tolerance:

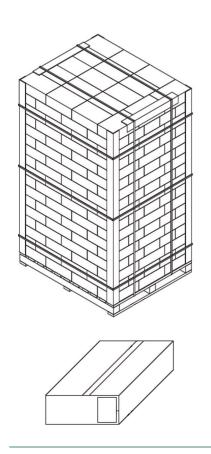
± 0.03 mm

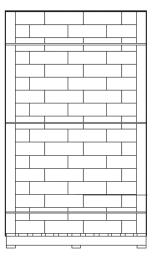
Durometer:

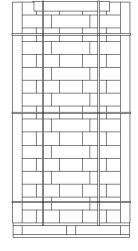
TBD

Packaging Dimensions

50 Each Per Box - Palletization Configuration



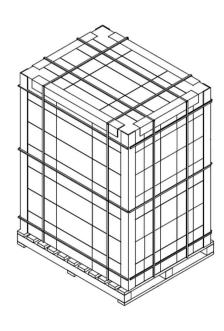




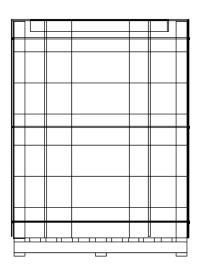
DM-102 DM-112 DM-113 DM-114 DM-115

Units Per Box	50
Boxes Per Pallet	105
Units Per Pallet	10,500
Box Configuration	3 x 5 x 7

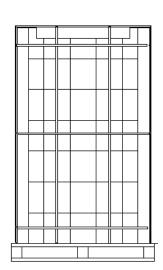
100 Each Per Box - Palletization Configuration







DM-103
DM-104
DM-105
DM-106
DM-107
DM-108
DM-109
DM-110
DM-111



Units Per Box	50
Boxes Per Pallet	105
Units Per Pallet	10,500
Box Configuration	3 x 5 x 7

Labeling Information



Manufactured For: DirectMed, Inc. 98 Pratt Oval Glen Cove, NY 11542-USA www.directmed.com Ph: 516-656-3377

manufactured with natural rubber latex. Federal Law (U.S.) restricts this device to sale by or on the order of a registered physician.



- Non Pyrogenic
- Sterile unless package

Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reactions or infections.



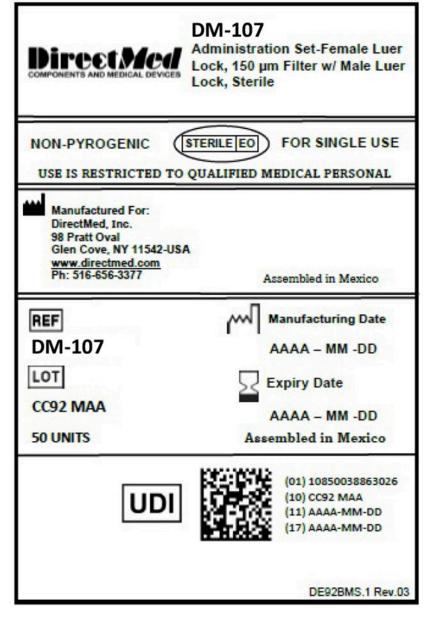


DM-107

00850038863029 CC92 MAA

AAAA-MM-DD

AAAA-MM-DD DE92BMS Rev. 03



DirectMed IFU



INSTRUCTIONS FOR USE

Administration Set

Female Luer Lock, 150 Micron Filter w/Male Luer Lock

MATERIALS USED

PVC, Non-DEPH, Latex free, BPA free

INDICATIONS:

o To prepare and deliver small aliquots of whole blood, cellular (red cells and platelets) components, and fresh-frozen plasma transfusion

DIRECTIONS

o Use per hospital protocol

CONTRAINDICATIONS

Product should not be used in patients with known hypersensitivity to any of the materials used.

- SUGGESTED INSTRUCTIONS FOR USE:
 oStandard clinical or hospital protocol must be established and performed by persons trained in the procedure and knowledgeable of the inherent risks.
 oInspect packing to ascertain that package is intact.
 oRemove the set from sterile packing while care must be taken to maintain product hygiene.
- o Check and secure ALL connections o Prime the set and make sure all air has been expressed before administration to patient.

PRIMING:
o Open the clamp and escape air entirely through ENTIRE LENGTH of PVC TUBE SET.

TERM OF USE:

"Syringe blood aliquots (RSC's and plasma) must be administered to patient within 24 hours and syringe platelet aliquots within 4 hours.

- WARNINGS

 The FDA Federal Law (USA) restricts this device for sale by or on the order of a physician.

 Standard clinical or hospital protocol must be established and performed by persons trained in the procedure and knowledgeable of the inherent risks.

 of there is any change in expected performance of the device or in case of any malfunction the device should be immediately removed & sent back to Supplier/manufacturer for analysis.

 of known/reported adverse events associated with use of this device, refer to the Complaint Report Form from Directffled, Inc.

 of IRCCTMED, INC. DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES RESULTING FROM IMPROPER USE of THE DEVICE.

 of Any device that is connected to this product must comply with EN 20594-1 & ISO 594-2. Incorrect connection or lose connection may cause leaking or air getting into blood vessel.
- oAny device that is commerce when the version of th

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Sterilized by Ethylene Oxide Gas

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Caution, Consult Accompanying



Consult Instructions for Use



Non-Pyrogenic



Do Not Use if Package is Damaged



Do Not resterilize



Keep away from sunlight

Non-DEHP

Not made with natural rubber

DE92BMS.2 Rev.01



At DirectMed, we are dedicated to providing our customers with the highest possible quality medical devices assembled in Mexico by our trusted manufacturing partners. We understand reliable and safe medical devices are paramount. This is why we guarantee that all products undergo a comprehensive series of tests to ensure the highest standards of safety and performance are being met. These include:

- Cytotoxicity test
- Sensitization Test
- Irritation Test (Including Intracutaneous Reactivity)
- Acute Systemic Toxicity Test
- Material Mediated Pyrogenicity Test
- Hemocompatibility Test (Hemolysis Direct/Indirect Method)
- Subacute and Sub-Chronic Toxicity Tests
- Chemical Test
- Shelf-Life Testing
- Sterility Test
- Peel Test
- Leak Test
- Pull Test

With these rigorous testing protocols for selected items, you can trust that our devices meet the highest safety standards.





Contact Us to Customize Your Set Today