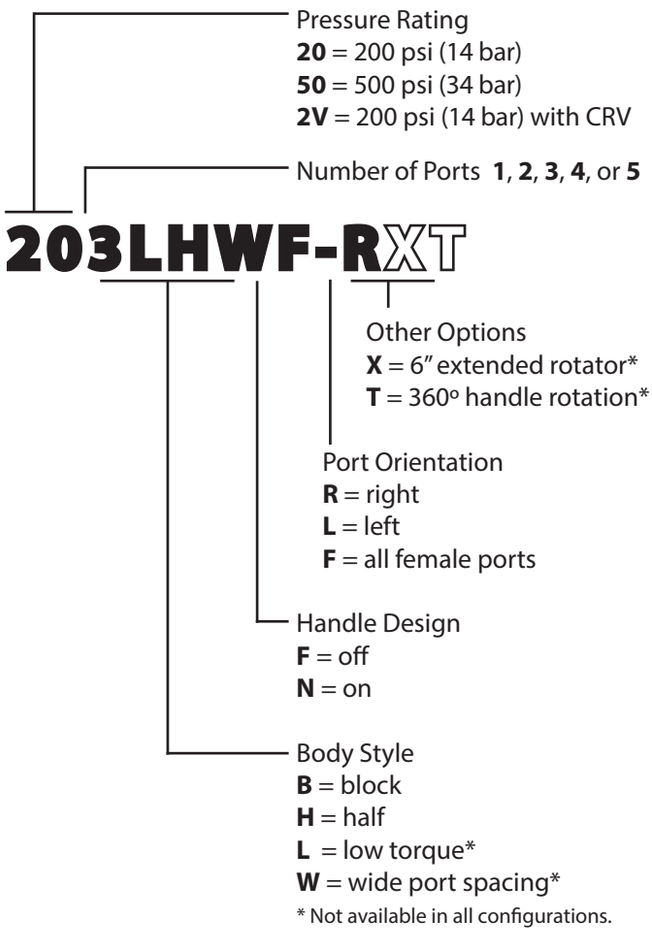
MERIT MANIFOLDS™

Product Description
The Merit manifold consists of a clear plastic body with colored handles that control the flow of fluids through multiple ports. The handles of the manifold are prominently marked with arrows indicating the direction of flow. The handles are easy to rotate but have sufficient torque to prevent inadvertent movement. Merit manifolds are available with various types of fitting connectors.

Catalog Numbers
Manifold catalog numbers are based on the following logic:



* Not available in all configurations.

Merit's DeVos manifolds area standard manifold with a check relief valve as the end port. The DeVos manifolds are available with:
- 2 or 3 port standard port spacing and 4 port wide
- Half body style
- Right port orientation
- 180°/360°
- 200 PSI (14 BAR) pressure rating
- OFF handles (ON handles)

Intended Use
Merit Manifolds are indicated for use in diagnostic and interventional applications to control or direct fluid flow between tubing, catheters, or other devices.

Contraindications
None known

Warning: Merit Manifolds are not recommended for use with lipids. Prolonged exposure to lipid solutions may result in stress cracking or leakage.

Precautions
- Carefully read instructions before using product. If product is being used in conjunction with other manufacturers' components, also read Instructions for Use.
- Use proper aseptic techniques while handling product.
- Inspect device prior to use to verify that no damage has occurred during shipping.
- Only use standard Luer connection devices. A standard Luer connection must conform to the harmonized standard ISO 594-2.
- DO NOT OVER-TIGHTEN connections.
- DO NOT USE any instrument to tighten connections.

REUSE PRECAUTION STATEMENT
For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

Instructions for Use
1. Using aseptic technique, open the package containing the sterile product.
2. Inspect for damage or improper assembly.
3. Check all connections before use and finger tighten.

Warning: To prevent stripping, do not over tighten.

4. Prime the manifold before use.

Note: Ensure all connections are securely tightened.

5. Inspect carefully for air bubbles and if necessary flush the lumen. Ensure that all air bubbles are removed.
6. Attach fluid devices/tubing. Ensure that all connections are secure.
7. Rotate the handles to the appropriate position to get the desired flow path.
   a. The molded arrows on the manifold handles indicate the open port flow paths.
   b. The molded "off" on the handle indicates a closed port preventing flow of fluid.

Single Use

Caution: Consult accompanying document

STERILE EO

Non-pyrogenic
Sterile if package is unopened or undamaged

℞ Only: Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Manufacturer: Merit Medical Systems, Inc.
1600 West Merit Parkway, South Jordan, Utah 84095
U.S.A. 1-801-253-1600 U.S.A. Customer Service 1-800-356-3748

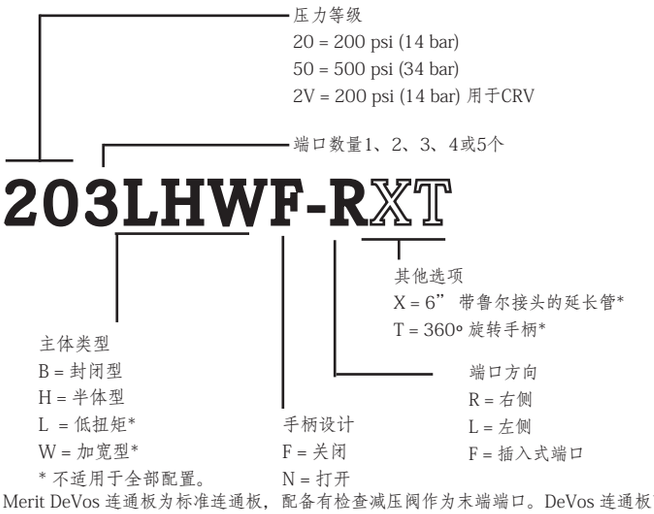
EC REP Authorized Representative: Merit Medical Ireland Ltd,
Parkmore Business Park West, Galway, Ireland +31 43 358 82 22

一次性使用连通板

使用说明

产品描述
Merit 一次性使用连通板由透明塑料主体和彩色手柄构成，这些手柄可以控制液体向多个端口流动。集合管的手柄标注有醒目的箭头标记，可以指示液体流动的方向。本产品的手柄易于旋转，但有足够的扭矩防止意外转动。Merit 连通板可以提供多种类型的接头连接器。

目录编号
连通板基于以下逻辑进行目录编号：



Merit DeVos 连通板为标准连通板，配备有检查减压阀作为末端端口。DeVos 连通板可提供：

- 2 或 3 个端口的标准端口间距产品和 4 个端口的宽间距产品
- 半块状阀体
- 端口方向朝向左侧
- 180º/360º
- 200 PSI （14 BAR）压力等级
- 关闭手柄 （打开手柄）

适用范围：用于临床血管造影或血管成形术中。
由连通止回阀组成的DeVos连通板用于心脏手术，以达到不使用操作手柄即可控制造影剂流向的目的。

禁忌症
尚不明确

警告：Merit 连通板不建议搭配脂类使用。
长时间暴露于脂类溶液可能会导致应力性破裂或渗漏。

注意事项

- 使用产品前请仔细阅读说明书。如果产品配合其他制造商的部件一起使用，也请阅读使用说明。
- 操作产品时，请使用适当的无菌操作。
- 使用前请先进行检查，确认运输过程中装置没有发生损坏。
- 仅能使用标准路厄连接装置。标准的路厄连接必须符合统一标准 ISO 594-2。
- 请勿过度旋紧连接。
- 请勿使用任何工具旋紧连接。

重复使用注意事项声明
仅限单个患者使用。请勿重复使用、再次加工或再次灭菌。重复使用、再次加工或再次灭菌可能会破坏装置的结构完整性和/或导致装置故障，这可能会导致患者受伤，患病或死亡。重复使用、再次加工或再次灭菌也可能会引发装置污染风险和/或导致患者感染或交叉感染，包括但不限于，传染病从一名患者传染给另一名患者。装置污染可能导致患者受伤、患病或死亡。

增塑剂名称：邻苯二甲酸二酯（DEHP）
警示信息及药物相容性提示：1）本产品不宜贮存和输注脂肪乳等脂溶性液体和药物；2）临床医务人员应注意其对高风险人群（新生儿、青春期前的男性、怀孕期和哺乳期的妇女）的可能毒性，应尽量替代。3）不能用于输注与PVC不相容的药物。

使用说明
1. 请采用无菌操作打开包含无菌产品的包装。
2. 请检查是否存在损坏或装配不当。
3. 请在使用和用手旋紧前检查全部连接。
警告：为防止磨损螺纹，请勿过度旋紧。
4. 使用前请先灌注连通板。
注意：请确保全部连接都已旋紧。
5. 请仔细检查是否存在气泡，如有必要，请冲洗管腔。
请确保已排出全部气泡。
6. 连接液体设备/管道。请确保全部连接都安全可靠。
7. 将手柄旋转到适当位置，以获得所需的流动通路。
   a. 连通板手柄上成型的箭头指示了开放的端口流动通路。
   b. 手柄上成型的“off”指示了关闭的端口，可以阻止液体流动。

不得二次使用

警告

STERILE EO 经环氧乙烷灭菌。
结构及组成：由连通板体（聚碳酸酯）、手柄（乙缩醛）、旋转体连接器接头（共聚酯）、止回阀门（聚碳酸酯）、延长管（聚氯乙烯DEHP）组成，其中使用的粘合剂为丙烯酸酯聚氨酯。环氧乙烷灭菌，一次性使用。

无热原
包装未打开和损坏时为无菌状态

储存条件：室温，通风，干燥，避光
运输条件：在运输过程中避免接触高温潮湿

℞ Only: 警告：(美国) 联邦法律规定本设备应由医师或遵照医嘱销售。

型号、规格：请见附录A
产品名称：一次性使用连通板
有效期：3年
注册人及生产企业名称：美国麦瑞通医疗设备有限公司 MERIT MEDICAL SYSTEMS, INC.
注册人及生产企业住所：1600 West Merit Parkway, South Jordan, Utah 84095
生产地址：1600 West Merit Parkway, South Jordan, Utah 84095
注册人及生产企业联系方式：1-801-253-1600
中国境内代理人及售后服务单位名称：麦瑞通医疗器械（北京）有限公司
中国境内代理人及售后服务单位住所：北京市朝阳区东大桥路9号楼2单元801室内B01、B02及B03单元
中国境内代理人及售后服务单位电话：010-85610788
中国境内代理人及售后服务单位传真：010-85616981
注册证编号：国械注进20152030718
产品技术要求编号：国械注进20152030718
生产日期和失效日期：见产品标签
说明书编制或修订日期：2022年8月

附录A 连通板型号表

编号	型号	描述
1	201BF-R	Manifolds,200PSI
2	202BF-L	Manifolds,200PSI
3	202BF-R	Manifolds,200PSI
4	202BN-F	Manifolds,200PSI
5	202BN-R	Manifolds,200PSI
6	202BN-RT	Manifolds,200PSI
7	202HF-F	Manifolds,200PSI
8	202HF-L	Manifolds,200PSI
9	202HF-R	Manifolds,200PSI
10	202HF-RX	Manifolds,200PSI
11	202HN-R	Manifolds,200PSI
12	202HN-RX	Manifolds,200PSI
13	203LHN-R	Manifolds,200PSI
14	203BF-FT	Manifolds,200PSI
15	203BF-L	Manifolds,200PSI
16	203LHWN-R	Manifolds,200PSI
17	203LHF-R	Manifolds,200PSI
18	203LHWF-R	Manifolds,200PSI
19	203BF-R	Manifolds,200PSI
20	203BF-RT	Manifolds,200PSI
21	203BF-RX	Manifolds,200PSI
22	203BF-RXT	Manifolds,200PSI
23	203BN-L	Manifolds,200PSI
24	203BN-R	Manifolds,200PSI
25	203BN-RT	Manifolds,200PSI
26	203HF-F	Manifolds,200PSI
27	203HF-L	Manifolds,200PSI
28	203HF-R	Manifolds,200PSI
29	203HF-RX	Manifolds,200PSI
30	203HN-R	Manifolds,200PSI
31	203HN-RX	Manifolds,200PSI
32	204BF-FT	Manifolds,200PSI
33	204BF-R	Manifolds,200PSI
34	204BF-RT	Manifolds,200PSI
35	204BF-RX	Manifolds,200PSI
36	204BF-RXT	Manifolds,200PSI
37	204BN-R	Manifolds,200PSI
38	204HF-FT	Manifolds,200PSI
39	204HF-R	Manifolds,200PSI
40	204HF-RT	Manifolds,200PSI
41	204HF-RX	Manifolds,200PSI
42	204HN-R	Manifolds,200PSI
43	205BF-F	Manifolds,200PSI
44	205BF-FT	Manifolds,200PSI
45	2V2HF-R	DeVos manifolds, 200PSI
46	2V3HF-R	DeVos manifolds, 200PSI
47	2V2HF-RT	DeVos manifolds, 200PSI
48	2V3HF-RT	DeVos manifolds, 200PSI
49	2V4LHWF-RT	DeVos manifolds, 200PSI
50	501BF-R	Manifolds, 500 PSI
51	501 BN-R	Manifolds, 500 PSI
52	502BF-L	Manifolds, 500 PSI
53	502BF-LT	Manifolds, 500 PSI
54	502BF-R	Manifolds, 500 PSI
55	502BF-RX	Manifolds, 500 PSI
56	502BN-R	Manifolds, 500 PSI
57	502HF-L	Manifolds, 500 PSI
58	502HF-R	Manifolds, 500 PSI
59	502HF-RT	Manifolds, 500 PSI
60	502HN-R	Manifolds, 500 PSI
61	503BF-F	Manifolds, 500 PSI
62	503BF-L	Manifolds, 500 PSI
63	503BF-R	Manifolds, 500 PSI
64	503BF-RT	Manifolds, 500 PSI
65	503BF-RX	Manifolds, 500 PSI
66	503LHN-R	Manifolds, 500 PSI
67	503LHWN-R	Manifolds, 500 PSI
68	503LHF-R	Manifolds, 500 PSI
69	503LHWF-R	Manifolds, 500 PSI
70	503BN-R	Manifolds, 500 PSI
71	503HF-L	Manifolds, 500 PSI
72	503HF-R	Manifolds, 500 PSI
73	503HF-RT	Manifolds, 500 PSI
74	503HF-RX	Manifolds, 500 PSI
75	503HN-R	Manifolds, 500 PSI
76	503HN-RX	Manifolds, 500 PSI
77	504BF-RT	Manifolds, 500 PSI
78	504BN-R	Manifolds, 500 PSI
79	504BN-RT	Manifolds, 500 PSI
80	504HF-R	Manifolds, 500 PSI
81	504HF-RX	Manifolds, 500 PSI
82	504HN-R	Manifolds, 500 PSI
83	504HN-RT	Manifolds, 500 PSI