

MANIFOLD

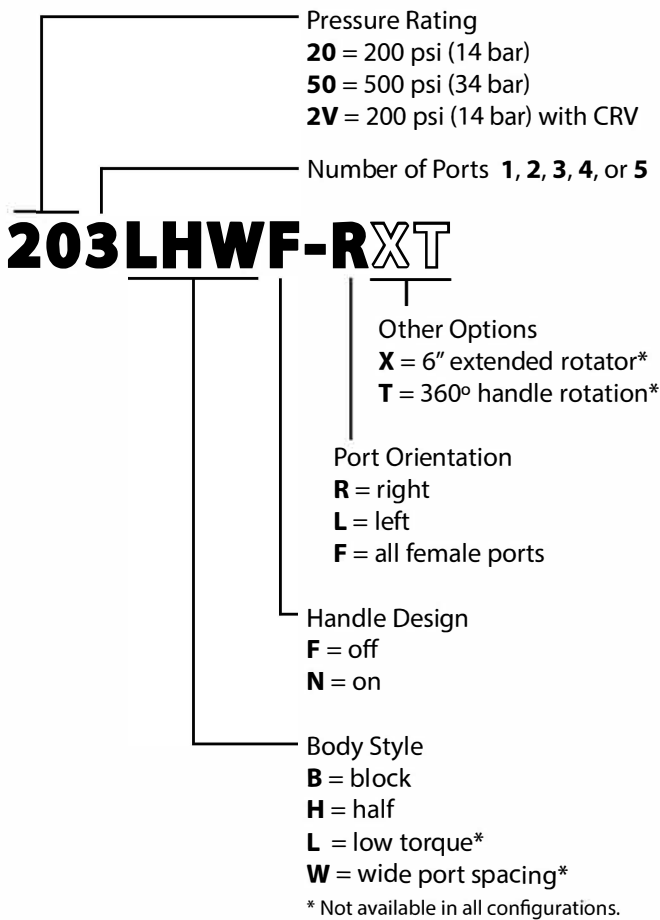
INSTRUCTION FOR USE

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:



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

- Using aseptic technique, open the package containing the sterile product.
 - Inspect for damage or improper assembly.
 - Check all connections before use and finger tighten.
- Warning:** To prevent stripping, do not over tighten.
- Prime the manifold before use.
- Note:** Ensure all connections are securely tightened.
 - Inspect carefully for air bubbles and if necessary flush the lumen. Ensure that all air bubbles are removed.
 - Attach fluid devices/tubing. Ensure that all connections are secure.
 - Rotate the handles to the appropriate position to get the desired flow path.
 - The molded arrows on the manifold handles indicate the open port flow paths.
 - 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

Rx 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

www.merit.com

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MERIT[®] 连通板

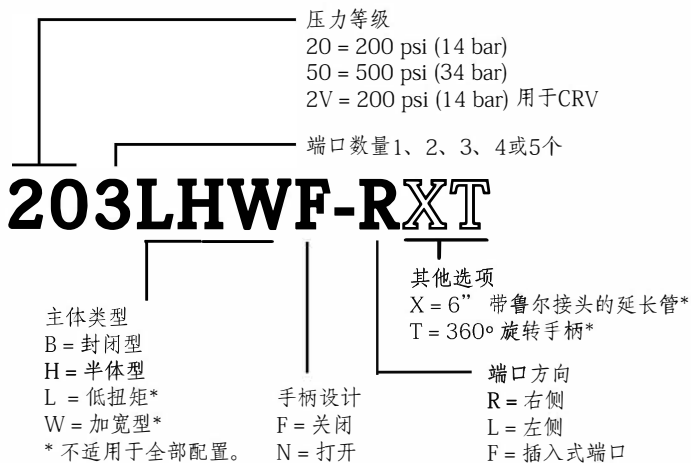
使用说明

产品描述：

Merit 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：



预期用途：该产品用于临床血管造影介入造影术。用于控制液体在管路之间的导向。

使用部位：与血液间接接触，接触时间≤24小时。

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。
- 产品使用必须符合医疗部门相关操作规范及相关法规的要求，仅限于经培训的医生或护理人员使用。

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。

使用说明

- 请采用无菌操作打开包含无菌产品的包装。
- 请检查是否存在损坏或装配不当。
- 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。
- 使用前请先灌注连通板。
注意：请确保全部连接都已旋紧。
- 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。
- 连接液体设备/管道。请确保全部连接都安全可靠。
- 将手柄旋转到适当位置，以获得所需的流动通路。
 - 连通板手柄上成型的箭头指示了开放的端口流动通路。
 - 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：



环氧乙烷灭菌

生产日期和失效日期，见产品标签。

有效期：3年。

注册证编号：国械注进20183660275

产品技术要求编号：国械注进20183660275

中国境内代理人及售后服务单位名称：美瑞通医疗器械（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

注册人及生产企业名称：Merit Medical Systems, Inc. 美国美瑞通医疗设备有限公司

注册人及生产企业住所，1600 West Merit Parkway, South Jordan, Utah 84095 USA

生产地址：1600 West Merit Parkway, South Jordan, Utah 84095 USA

注册人及生产企业联系方式：1-801-253-1600

说明书编制或修订日期：2021年9月

产品名称：连通板

适用范围：用于临床血管造影介入造影术。用于控制液体在管路之间的导向。压力等级 有200PSI 和500PSI，通常情况下，高压注射的时间是1到4秒。

结构及组成：连通板由连通板体(聚碳酸酯)、手柄(乙缩醛)、旋转体连接器接头(聚碳酸酯)、止回阀门(聚碳酸酯)、延长管(聚氯乙烯 含柠檬酸酯)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。

型号、规格：附录A 连通板规格型号表

型号	端口数量	长度 (cm)	宽度 (cm)	端口间距 (cm)	描述
201BF-R	1	6.05-7.47	3.55-3.69	无	Manifolds, 200PSI
202BF-L	2	9.40-11.48	3.55-3.69	3.58-4.02	Manifolds, 200PSI
202BF-R	2	9.40-11.48	3.55-3.69	3.58-4.02	Manifolds, 200PSI
202BN-F	2	6.81-8.79	3.55-3.69	3.58-4.02	Manifolds, 200PSI
202BN-R	2	9.40-11.48	3.55-3.69	3.58-4.02	Manifolds, 200PSI
202BN-RT	2	9.40-11.48	3.55-3.69	3.58-4.02	Manifolds, 200PSI
202HF-F	2	6.81-8.79	3.55-3.69	3.58-4.02	Manifolds, 200PSI
202HF-L	2	9.40-11.48	3.55-3.69	3.58-4.02	Manifolds, 200PSI
202HF-R	2	9.40-11.48	3.55-3.69	3.58-4.02	Manifolds, 200PSI
202HF-RX	2	19.82-26.89	3.55-3.69	3.58-4.02	Manifolds, 200PSI
202HN-R	2	9.40-11.48	3.55-3.69	3.58-4.02	Manifolds, 200PSI
202HN-RX	2	19.82-26.89	3.55-3.69	3.58-4.02	Manifolds, 200PSI
203LHN-R	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 200PSI
203BF-FT	3	10.16-12.80	3.55-3.69	3.58-4.02	Manifolds, 200PSI
203BF-L	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 200PSI
203LHWN-R	3	13.64-16.38	3.55-3.69	3.79-4.46	Manifolds, 200PSI
203LHF-R	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 200PSI
203LHWF-R	3	13.64-16.38	3.55-3.69	3.79-4.46	Manifolds, 200PSI
203BF-R	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 200PSI
203BF-RT	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 200PSI
203BF-RX	3	23.18-30.90	3.55-3.69	3.58-4.02	Manifolds, 200PSI
203BF-RXT	3	23.18-30.90	3.55-3.69	3.58-4.02	Manifolds, 200PSI
203BN-L	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 200PSI
203BN-R	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 200PSI
203BN-RT	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 200PSI
203HF-F	3	10.16-12.80	3.55-3.69	3.58-4.02	Manifolds, 200PSI
203HF-L	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 200PSI
203HF-R	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 200PSI
203HF-RX	3	23.18-30.90	3.55-3.69	3.58-4.02	Manifolds, 200PSI
203HN-R	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 200PSI
203HN-RX	3	23.18-30.90	3.55-3.69	3.58-4.02	Manifolds, 200PSI
204BF-FT	4	13.51-16.81	3.55-3.69	3.58-4.02	Manifolds, 200PSI
204BF-R	4	16.10-19.50	3.55-3.69	3.58-4.02	Manifolds, 200PSI
204BF-RT	4	16.10-19.50	3.55-3.69	3.58-4.02	Manifolds, 200PSI
204BF-RX	4	26.53-34.91	3.55-3.69	3.58-4.02	Manifolds, 200PSI
204BF-RXT	4	26.53-34.91	3.55-3.69	3.58-4.02	Manifolds, 200PSI
204BN-R	4	16.10-19.50	3.55-3.69	3.58-4.02	Manifolds, 200PSI
204HF-FT	4	13.51-16.81	3.55-3.69	3.58-4.02	Manifolds, 200PSI
204HF-R	4	16.10-19.50	3.55-3.69	3.58-4.02	Manifolds, 200PSI
204HF-RT	4	16.10-19.50	3.55-3.69	3.58-4.02	Manifolds, 200PSI

204HF-RX	4	26.53-34.91	3.55-3.69	3.58-4.02	Manifolds, 200PSI
204HN-R	4	16.10-19.50	3.55-3.69	3.58-4.02	Manifolds, 200PSI
205BF-F	5	16.86-20.82	3.55-3.69	3.58-4.02	Manifolds, 200PSI
205BF-FT	5	16.86-20.82	3.55-3.69	3.58-4.02	Manifolds, 200PSI
501BF-R	1	6.05-7.47	3.55-3.69	无	Manifolds, 500 PSI
501BN-R	1	6.05-7.47	3.55-3.69	无	Manifolds, 500 PSI
502BF-LT	2	9.40-11.48	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
502BF-R	2	9.40-11.48	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
502BF-RX	2	19.82-26.89	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
502BN-R	2	9.40-11.48	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
502HF-L	2	9.40-11.48	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
502HF-R	2	9.40-11.48	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
502HF-RT	2	9.40-11.48	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
502HN-R	2	9.40-11.48	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
503BF-F	3	10.16-12.80	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
503BF-L	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
503BF-R	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
503BF-RT	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
503BF-RX	3	23.18-30.90	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
503LHN-R	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
503LHWN-R	3	13.64-16.38	3.55-3.69	3.79-4.46	Manifolds, 500 PSI
503LHF-R	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
503LHWF-R	3	13.64-16.38	3.55-3.69	3.79-4.46	Manifolds, 500 PSI
503BN-R	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
503HF-L	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
503HF-R	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
503HF-RT	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
503HF-RX	3	23.18-30.90	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
503HN-R	3	12.75-15.49	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
503HN-RX	3	23.18-30.90	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
504BF-RT	4	16.10-19.50	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
504BN-R	4	16.10-19.50	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
504HF-R	4	16.10-19.50	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
504HF-RX	4	26.53-34.91	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
504HN-R	4	16.10-19.50	3.55-3.69	3.58-4.02	Manifolds, 500 PSI
504HN-RT	4	16.10-19.50	3.55-3.69	3.58-4.02	Manifolds, 500 PSI