MyClip™
Transcatheter Edge To Edge Repair System
Restoring Life

# INSTRUCTIONS FOR USE

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| **Device Name** | MyClip™ Transcatheter Edge To Edge Repair (TEER) System |
| **Generic Name** | Transcatheter Edge To Edge Repair (TEER) System |
| **Brand Name** | MyClip™<br><br>MyClip is a registered trade mark of-<br>Meril Medical Innovations Private Limited. |
| **Manufacturer details** | Meril Medical Innovations Private Limited.<br>Meril Park 1, F2, F3, F5 and<br>Meril Park 2, F5, F6 Survey No. 879,<br>Muktanand Marg, Chala, Vapi, Valsad,<br>Gujarat, 396191. India.<br><br>W : www.merillife.com<br>Customer Care Contact :<br>T : +91 (260) 240 8000<br>E : askinfo@merillife.com |
| **CDSCO License No.** | MFG/MD/2024/000616 |

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| **User Attention, Precaution and Warning** | MyClip TEER System cannot be purchased by an individual patient and is sold only to tertiary care hospitals with advanced muti-disciplinary Cardiology Expert Heart Team involving well trained and qualified health care professionals supported by but not limited to cardiac intensive care units, cardiac catheterization labs, 3D transoesophageal echocardiography (TEE) / transthoracic echocardiographic (TTE) and cardiovascular thoracic surgery facility.<br><br>MyClip TEER System is recommended to be used only by qualified physicians trained to perform structural heart interventions and proficient in transcatheter edge to edge repair procedure using multi-modal imaging such as 3D TEE and Fluoroscopy.<br><br>Failure to follow MyClip TEER System IFU and recommended procedural techniques may lead to sub-optimal device performance and/or patient injury. |

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| Section 1.0 | Intended Use |
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| **Intended Use** | MyClip Transcatheter Edge to Edge Repair (TEER) System is indicated for the percutaneous repair of symptomatic mitral valve regurgitation (MR) in patients with following conditions who have been judged by expert heart team (may include interventional cardiologist, echocardiologist, cardiothoracic surgeon etc.) in patients who are at high risk of open surgical therapy and are suitable for percutaneous valve repair therapy.<br><br>Significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be at high or prohibitive risk for mitral valve surgery and are favourable for transcatheter approach and life expectancy >1 year.<br><br>Moderate-to-severe or severe secondary (or functional) mitral regurgitation related to LV left ventricular ejection fraction (LVEF < 50%) who have persistent symptoms (NYHA class II, III, or IV) while on optimal (guideline-directed management and therapy (GDMT) supervised by HF specialist, TEER is reasonable in patients with appropriate anatomy as defined on Transesophageal echocardiography (TEE) and with LVEF between 20% and 50%, and a left ventricular end systolic dimension (LVESD) ≤70mm. |
| **Intended Purpose** | The MyClip TEER System is intended to treat symptomatic Mitral Valve Regurgitation (MR). |
| **Patient Target Group** | Patients diagnosed with symptomatic primary degenerative mitral regurgitation (DMR) or those suffering from moderate to severe secondary functional mitral regurgitation (FMR). |
| **Intended User Group** | MyClip TEER System is designed for utilization by physicians who are proficient in structural heart interventions, interventional cardiology, endovascular interventions and deeply understand heart failure management, transcatheter edge to edge repair (TEER) of mitral valve procedures using multi modal imaging such as 3D TEE, fluoroscopy and other necessary cardiac catheterization techniques. |

| Section 2.0 | Contraindications |
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| **Absolute Contra-indications** | MyClip TEER System and TEER therapy are unsuitable in patients with following conditions :<br>• Known hypersensitivity to any materials used in implantable MyClip such as Cobalt Chromium, Polyester, Nitinol.<br>• Know hypersensitivity to anaesthetic agents, contrast media, and heparin, anti-platelet / anticoagulation agents.<br>• Inadequate leaflet anatomy not amenable to TEER procedure<br>o Leaflet length too short for adequate grasp (<5 mm typically).<br>o Excessive coaptation gap (>10 mm in MR).<br>o Severe calcification at grasping zone or retracted leaflets, mitral annular calcification.<br>o Perforated, cleft or torn leaflet not amenable to edge to edge repair.<br>• Significant Mitral Valve Stenosis<br>o Mitral valve area <4.0 $cm^2$ pre-procedure.<br>o Mean gradient >4 mmHg at baseline or expected to exceed >6 mmHg post-clip.<br>o Presence of active endocarditis or sepsis.<br>o Any active infection which can increase risk of prosthetic infection and sepsis.<br>o Rheumatic mitral valve disease.<br>• Evidence of intra-cardiac thrombus especially in left ventricle, inferior vena cava or femoral vein.<br>• Inability to perform transseptal access<br>o Due to prior atrial septal device, or congenital anomaly. |
| **Relative Contra-indications** | • Severe pulmonary hypertension (PASP >50 mmHg).<br>• Significant right heart failure.<br>• Life expectancy <1 Year.<br>• Severely reduced LV function ($\leq$ 20%) without contractile reserve. |

| Section 3.0 | Warnings |
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| Warnings | • This product is intended solely for the indications specified.<br>• Thoroughly review all instructions before use. Failure to adhere to the specified instructions, warnings, and precautions may lead to sub-optimal device performance or lead to inadvertent injury to the patient.<br>• Inspect the product packaging carefully before use. Do not use if the product packaging is opened, unsealed or damaged.<br>• Do not use the device if packaging is damaged or expired.<br>• Single Use Only<br>  o MyClip Guide Catheter (MGC), MyClip Delivery System (MDS) are sterile and intended for single use only. Reprocessing such as cleaning, re-sterilization or reuse can result in infection, mechanical device failure, or serious injury, including death.<br>• Device Embolization or Detachment<br>  o Incomplete leaflet grasp or improper deployment may cause clip embolization, a serious event potentially requiring surgical retrieval.<br>• Avoid Excessive Manipulation<br>  o Forceful catheter or device manipulation can lead to :<br>  ▪ Leaflet damage<br>  ▪ Chordal rupture<br>  ▪ Cardiac perforation<br>• Proper Imaging is Critical<br>  o Real-time 3D transoesophageal echocardiography (TEE) and fluoroscopy are essential for :<br>  ▪ Transseptal puncture<br>  ▪ Accurate positioning<br>  ▪ Confirming leaflet insertion<br>  ▪ Avoiding suboptimal deployment<br>• Mitral Valve Gradient<br>  o Implanting too many clips or a large clip in a small valve can raise the trans mitral gradient, risking iatrogenic mitral stenosis<br>  o **Warning :** mean gradient ≥ 4 mmHg pre-procedure<br>• Clip-Arms Locking Failure<br>  o If the Clip-Arms do not lock properly (or remain open > 20°), do not deploy the MyClip device. A locked but ungrasped clip may :<br>  ▪ Dislodge<br>  ▪ Fail to reduce MR<br>  ▪ Require surgical conversion |

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| | • Avoid Interference with Cardiac Structures<br>  o Care must be taken to avoid damage to :<br>  ▪ Aortic valve<br>  ▪ Left atrium – roof, posterior wall<br>  ▪ Coumadin ridge<br>  ▪ Left atrial appendage (LAA)<br>  ▪ Chordae tendineae and papillary muscles<br>• MRI Safety<br>  o Patients can undergo MRI under specific conditions :<br>  ▪ MRI conditional (e.g., 1.5T or 3.0T with limits on SAR).<br>  ▪ Must follow MRI guidelines as per this IFU to avoid clip heating or migration.<br>• Patient anatomical considerations which may prohibit use of MyClip<br>  o Heavy mitral annular or leaflet calcification in grasp area.<br>  o Flail width >15 mm or flail gap >10 mm (relative contraindication, depending on clip model).<br>• Additional Notes :<br>  o The use of the device is restricted to physicians who are trained and proficient in structural heart interventions, interventional cardiology, endovascular interventions, transseptal puncture as well as multi modal imaging such as 3D TEE, fluoroscopy, as well as in the proper operation of the system.<br>  o The procedure must be performed in a hospital equipped with adequate facilities for cardiac surgery and immediate access to cardiac operating rooms.<br>  o Always use the complete system MGC, MDS as per IFU. MGC and MDS are not tested for compatibility with other known predicate TEER systems and may lead to product failure and or harm to the patient. |

| **Section 4.0** | **Precautions** |
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| Precautions | • Pay attention to the "Shelf life" marked on the product packaging.<br>• Check all products before use and do not use it if the packaging or the product is damaged.<br>• Please refer to the instructions for use of any interventional device used in conjunction with this device for its intended purposes, dimensions, warnings and precautionary measures.<br>• After use, the product and packaging should be disposed of in accordance with the policies of the hospital, administrative department or local regulations. |

| Section 5.0 | Potential Complications & Adverse Events During Mitral TEER Procedure |
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| | • **Allergic & Immune Reactions :** Allergic reaction (to anaesthetic agents, contrast media, heparin, cobalt chromium, polyester, Nickel alloy), drug reaction to anti-platelet/ anticoagulation agents/ contrast media, fever or hyperthermia, septicaemia, infection and pain at insertion/incision site, wound dehiscence.<br><br>• **Cardiac Complications :** Aneurysm or pseudo-aneurysm, cardiac arrhythmias, cardiac arrest, cardiac perforation, cardiac tamponade/ pericardial effusion, myocardial infarction, prolonged angina, stroke or transient ischemic attack (TIA), worsening heart failure, emboli (air, thrombus, clip device), emergency cardiac surgery, conversion to standard valve surgery.<br><br>• **Clip Specific Risks :** Clip erosion, migration or malapposition, clip device thrombosis, clip system component(s) embolization, single leaflet device attachment (SLDA), failure to deliver or retrieve clip components, injury to mitral valve complicating or preventing surgical repair, mitral stenosis, mitral valve injury, worsening of mitral regurgitation.<br><br>• **Pulmonary Complications :** Dyspnoea, pulmonary congestion, pulmonary thrombo-embolism, respiratory failure/ atelectasis/ pneumonia, prolonged ventilation.<br><br>• **Neurological Complications :** Stroke or transient ischemic attack (TIA).<br><br>• **Vascular & Hematologic Complications :** Arterio-venous fistula, deep venous thrombus (DVT), coagulopathy, hematoma, homolysis, haemorrhage requiring transfusion, vascular trauma, dissection or occlusion, vessel spasm, bessel perforation or laceration, lymphatic complications.<br><br>• **Gastrointestinal & Renal Issues :** Gastrointestinal bleeding or infarct, nausea/vomiting, mesenteric ischemia, renal insufficiency or failure, urinary tract infection.<br><br>• **Device-Related Complications :** Dislodgement of previously implanted devices, skin injury or tissue changes due to ionizing radiation. |

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| | • **Systemic or Other Complications :** Oedema, hypotension / hypertension, multi-system organ failure, endocarditis, oesophageal irritation, perforation, or stricture, death.<br>• **Surgical and Procedural Complications :** Infection and pain at the incision site, wound dehiscence, surgical repair (necessitated by complication).<br>• **Respiratory Issues :** Prolonged oxygen uptake, dizziness (potentially linked to hypoxia or hypotension). |

| **Section 6.0** | **MyClip TEER System and Accessories** |
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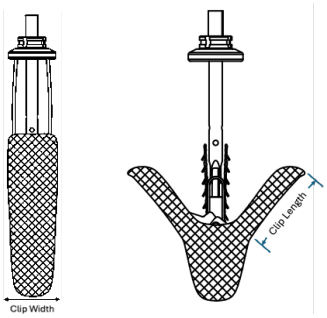
| MyClip TEER System | • MyClip Guide Catheter (MGC)<br>o Includes dedicated Dilator<br>▪ Sterile \| Single Use \| Quantity : One (01) |
| | • MyClip Delivery System (MDS)<br>o With pre-mounted, size specific implantable MyClip<br>▪ Sterile \| Single Use \| Quantity : One (01) |
| MyClip TEER System Accessories | • MyClip Accessories :<br>o Ground-Plate<br>▪ Non-sterile \| Reusable \| Quantity : One (01)<br>o Podium<br>▪ Non-sterile \| Reusable \| Quantity : One (01)<br>o Anti-Skid Silicone Mat<br>▪ Sterile \| Single use \| Quantity : One (01)<br>o Bracket<br>▪ Sterile \| Reusable \| Quantity : One (01)<br>o Bracket Fasteners<br>▪ Sterile \| Reusable \| Quantity : Three (03) |

<table>
<tr><td>Section 7.0</td><td>MyClip TEER System : Size Matrix & Ordering Information</td></tr>
<tr><td>MyClip Sizing Rationale</td><td>MyClip sizing rationale is based on the following well established criteria derived from Transoesophageal Echocardiography (TEE) -<ul><li>Location of the MR</li><li>Leaflet length and thickness</li><li>Coaptation/ flail gap</li><li>Jet characteristics</li><li>Mitral valve area</li><li>Mitral annular dimensions and anatomy</li></ul></td></tr>
<tr><td></td><td>Approved Implantable MyClip with ordering information<br><br>
<table>
<tr><td rowspan="2">MyClip Size Matrix</td><td>Clip Width →</td><td colspan="2">Regular</td><td colspan="2">Wide</td><td>Extra-Wide</td></tr>
<tr><td>Clip Length ↓</td><td>3 mm</td><td>4 mm</td><td>5 mm</td><td>6 mm</td><td>7 mm</td></tr>
<tr><td>Short</td><td>9 mm</td><td>MDS-SR0903</td><td>MDS-SR0904</td><td>MDS-SW0905</td><td>MDS-SW0906</td><td>MDS-SX0907</td></tr>
<tr><td>Long</td><td>12 mm</td><td>MDS-LR1203</td><td>MDS-LR1204</td><td>MDS-LW1205</td><td>MDS-LW1206</td><td>MDS-LX1207</td></tr>
</table>
<br>Note : Check availability of a particular MyClip size with Meril representative during pre-planning phase.</td></tr>
<tr><td></td><td>Key to understand MyClip ordering information<br><br> 

<br><br>Figure 01. MyClip Dimensions</td></tr>
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| | Clip Length is represented as Short (S) and Long (L)<br>Clip Width is represented as Regular (R), Wide (W) and Extra-wide (X)<br><br>• MDS – SR0903 : Short x Regular (9 X 3 mm)<br>• MDS – SR0904 : Short x Regular (9 X 4 mm)<br>• MDS – SW0905 : Short x Wide (9 X 5 mm)<br>• MDS – SW0906 : Short x Wide (9 X 6 mm)<br>• MDS – SX0907 : Short x Extra-Wide (9 X 7 mm)<br><br>• MDS – LR0903 : Long x Regular (12 X 3 mm)<br>• MDS – LR0904 : Long x Regular (12 X 4 mm)<br>• MDS – LW0905 : Long x Wide (12 X 5 mm)<br>• MDS – LW0906 : Long x Wide (12 X 6 mm)<br>• MDS – LX0907 : Long x Extra-Wide (12 X 7 mm) |
| MyClip Guide Catheter (MGC) ordering information | • MGC – MGC160800 : 24 Fr 80 cm |
| Ground-Plate ordering information | • MYCGP |
| Podium ordering information | • MYCPD |
| Bracket ordering information | • MYCBR |
| Anti-Skid Silicone Mat ordering information | • MYCASM |

| Section 8.0 | MyClip TEER System : Technical Specifications |
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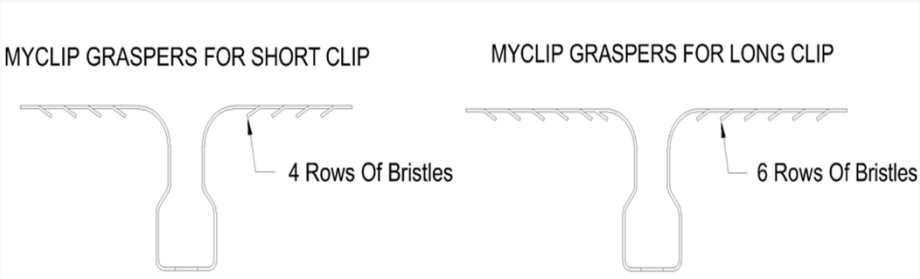
| Implantable MyClip | Materials of Construction :<br>• Clip-Arms : Cobalt Chromium covered with Polyester fabric<br>• Graspers : Nitinol |
| | Clip-Arms Widths :<br>• Regular (R) : 3 mm, 4 mm<br>• Wide (W) : 5 mm, 6 mm<br>• Extra-Wide (X) : 7 mm |
| | Clip-Arms Lengths :<br>• Short (S) : 9 mm<br>• Long (L) : 12 mm |
| | Graspers :<br>• Complementing each implantable Clip-Arm is a Nitinol Grasper with two longitudinal columns of anti-slip bristles facilitating secure leaflet grasping.<br>• Each set of bristles are placed 1.5 mm apart from each other.<br>• Short (S) Clip the grasping zone is 6 mm.<br>o 4 rows of bristles<br>• Long (L) Clip the grasping zone is 9 mm.<br>o 6 rows of bristles.<br>(as shown in Figure 02)<br>  <br>**Figure 02. MyClip Graspers** |

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| MyClip Delivery System (MDS) | Materials of Construction :<br>• Braided Pebax and Nylon |
| | • Working length : 112 cm<br>• Outer diameter : 18 Fr |
| | • Nitinol Grasper-Line : Nitinol wire running distally through the grasper mechanism.<br>• Nylon Clip-Lock-Line : Nylon suture running distally through the clip arm mechanism. |
| MyClip Guide Catheter (MGC) | Materials of Construction :<br>• Braided Pebax and Nylon |
| | • Working length : 80 cm<br>• Hydrophilic coating on outer shaft<br>• Shaft outer diameter<br>  • Distal 3.5 cm-22 Fr<br>  • Proximal 76.5 cm-24 Fr |
| MyClip Guide Catheter (MGC) Dilator | Materials of Construction :<br>• Pebax and Vestamid |
| | • Working length : 103 cm<br>• Outer diameter : 20 Fr<br>• Guidewire Compatibility : 0.035” (0.89 mm) |
| Ground Plate | • Acrylic (PMMA sheet), Stainless Steel (SS316L) hinges |
| Podium | • Stainless Steel (SS316L) |
| Bracket | • Stainless Steel (SS316L)<br>• Aluminium casing for storage |
| Anti-Skid Silicone Mat | • Silicone |

| Section 9.0 | MyClip TEER System : Storage & Transportation Conditions |
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| | • Storage Condition : Store in cool, dry and dark place in its original packaging.<br>• Transportation Condition : Products should be protected from heavy pressure, direct sunlight and rain during transportation. |

| Section 10.0 | MyClip TEER System & Accessories : Shelf Life |
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| | • MyClip Guide Catheter (MGC) : 2 years |
| | • MyClip Delivery System (MDS) : 2 years |
| | • Anti-Skid Silicone Mat : 2 years |
| | • Ground Plate : Non-sterile, reusable |
| | • Podium : Non-sterile, reusable |
| | • Bracket : Sterile, reusable |

| Section 11.0 | MyClip TEER System : MRI Compatibility |
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| | • MyClip is MRI conditional.<br>• Device Composition : Made of materials (cobalt-chromium and polyester) shown to be non-ferromagnetic and MRI-safe under conditional parameters.<br>• Patients with an implanted MyClip may safely undergo an MRI under the following conditions :<br>o Static magnetic field strength : 1.5 to 3.0 Tesla<br>o Bandwidth : 32kHz (required)<br>o Maximum spatial gradient magnetic field : ≤ 2,500 Gauss/cm.<br>o Specific Absorption Rate (SAR) : Whole-body SAR should not exceed 4.0 W/kg for 15 minutes of scanning (normal operating mode).<br>• Time after implantation : MRI may be performed immediately post-implantation. |

| Section 12.0 | MyClip TEER System – Device Description, Associated Terminology During TEER Procedure |
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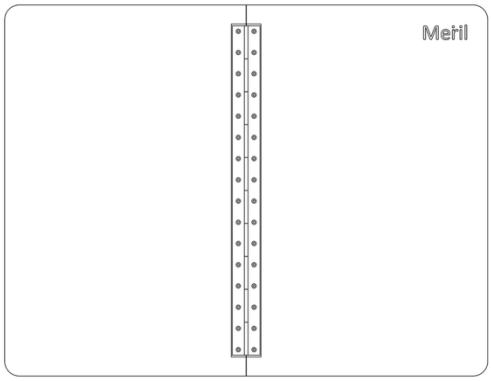
| MyClip Ground-Plate | • The MyClip Ground-Plate is provided in clean but non-sterile condition.<br>• The Ground-Plate is originally in folded condition across the single hinge.<br>• Unfold the Ground-Plate with Meril logo facing upward (as shown in the Figure 03)<br>• Place the Ground-Plate beneath the Patient's index leg across the knee joint on the Cath-Lab table.<br>• Stabilize other accessories over the Ground-Plate.<br>  <br>**Figure 03. MyClip Ground-Plate**<br>**Note :** Ground-Plate should be cleaned with standard hospital surfactants/disinfectants, dried and kept in clean dry place for future reuse. |
| MyClip Podium | • The MyClip Podium is provided in clean but non-sterile condition.<br>• The Podium is originally with all four legs stationed at same height (as shown in the Figure 04).<br>• Depending on the angle requirement, the fore-legs (towards the patient's heart) can be adjusted by pressing the buttons on telescopic legs.<br>• Place the height adjusted Podium above the Ground-Plate and ensures its stability.<br>• The distal edge of the Podium (towards the patient's heart) is recommended to be placed at 80 cm from the mid-sternum.<br>• A sterile drape can now be placed covering the patient and the Podium. |

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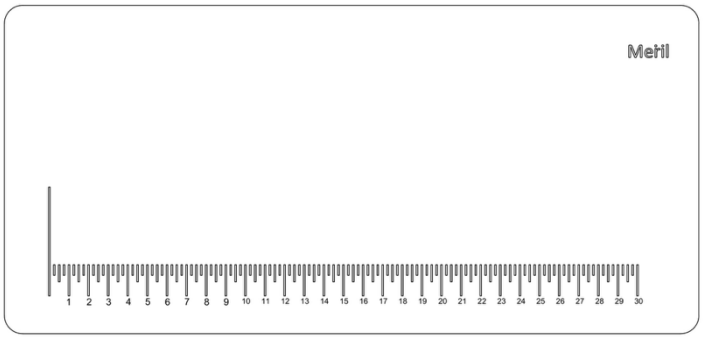
| | • All subsequent sterile accessories and sterile MyClip TEER system will be placed on the Podium covered with sterile drape.<br>  <br>**Figure 04. MyClip Podium**<br>• **Note :** Podium should be cleaned with standard hospital surfactants/disinfectants, dried and kept in clean dry place for future reuse. |
| MyClip Anti-Skid Silicone Mat | • The MyClip Anti-Skid Silicone Mat is provided in sterile condition and is for single use only.<br>• The Anti-Skid Silicone Mat is printed on one side with Meril logo and a centimetre scale measuring 30 cm.<br>• The Anti-Skid Silicone Mat is placed using sterile techniques on top of the draped surface of the Podium with Meril logo facing up (as shown in the Figure 05).<br>  <br>**Figure 05. MyClip Anti-Skid Silicone Mat** |

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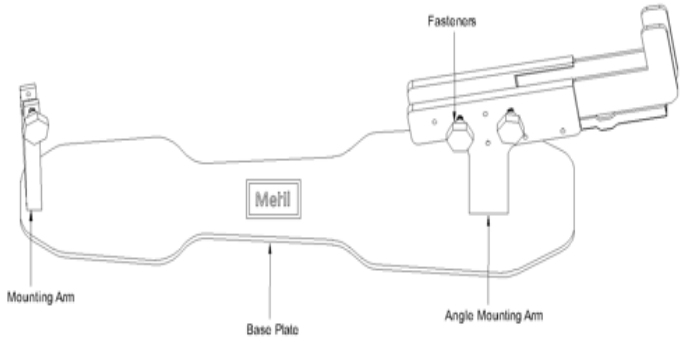
| MyClip Bracket | • The MyClip Bracket is provided in sterile condition and is reusable.<br>• The base plate of the Bracket is tapered shaped at its distal end (towards the patient's heart) and has a mounting arm with a fastening slot for holding the MGC.<br>• The proximal base plate of the Bracket is broader and has an angled mounting arm which houses the MDS securely at three pre-designated positions and can be fastened as per the anatomical requirement. (as shown in the Figure 06)<br>• Three (03) sterile Fasteners are provided along with the Bracket.<br>• Place the sterile Bracket using aseptic techniques on top-of the previously placed Anti-Skid Silicone Mat with Meril logo facing upwards.<br>  <br>**Figure 06. MyClip Bracket**<br><br>**Note :** MyClip Bracket can be cleaned with standard surfactants/disinfectant, dried prior to autoclave sterilization as per standard hospital protocols and kept in its dedicated aluminium casing in a clean dry place for future reuse using standard aseptic conditions. |
| MyClip Guide Catheter (MGC) | • The MyClip Guide Catheter (MGC) is provided in sterile condition and is single use only.<br>• The sterile outer casing houses one unit of the MGC and one unit of its dedicated Dilator. (as shown in the Figure 07)<br>• The retrieval of the MGC and its Dilator from the sterile casing is recommended to be done under standard sterile, aseptic conditions only by a trained person.<br>• The working length of MGC is 80 cm and has a profile of 22 Fr at its distal 3.5 cm MGC flexion zone with a radiopaque distal tip while maintaining 24 Fr profile throughout the residual catheter length.<br>• The outer shaft of MGC is hydrophilic coated to ensure smooth entry within the vasculature. |

- Proximally the MGC catheter merges into its Hub via a MGC Connecting Sleeve.
- A standard one-way MGC haemostatic valve with a black aligner marker line and a side port is provided proximal to the MGC Hub.
- Anteriorly, the MGC Hub has a bi-directional flexion knob indicating MGC Flex (+) and MGC Straight (-) Knob signs and a flexion free zone indicated by two red dots.
- MGC Flex (+) Knob rotation flexes the distal MGC tip, and MGC Straight (-) Knob rotation straightens the distal MGC tip.
- These movements can be used as per the anatomical requirements during TEER procedure.
- A bi-directional arrow marking on the lateral side of the MGC Hub indicating the MGC Anterior (A) / MGC Posterior (P) rotation allows MGC movement as required during the TEER procedure.
- The MGC Dilator has a profile of 20 Fr with working length of 103 cm, and it is compatible to 0.035" (0.89 mm) guidewire system.
- After positioning the MGC in left atrium of the patient, it is recommended to fasten the MGC Connecting Sleeve on the distal end of the Bracket slot above its mounting arm.

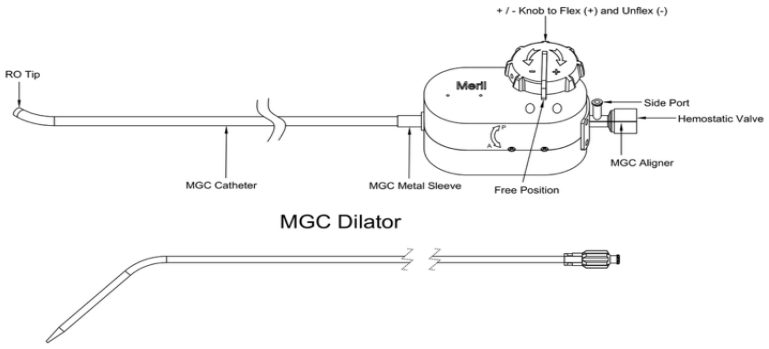



**Figure 07. MyClip Guide Catheter (MGC)**

- **Note :** It is recommended not to flex the MGC beyond 90° to prevent device malfunctioning/trauma.

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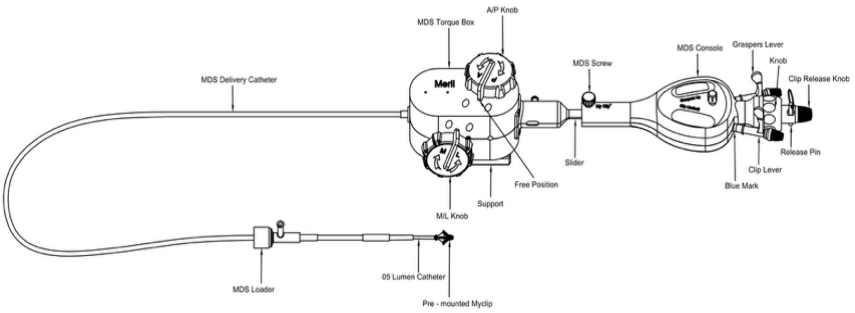
| MyClip Delivery System (MDS) | • The MyClip Delivery System (MDS) with a pre-mounted implantable MyClip is provided in sterile condition and is single use only.<br>• The sterile outer casing houses one unit of the size specific MDS.<br>• The retrieval of the MDS from its sterile casing is recommended to be done under standard sterile, aseptic conditions only by a trained person.<br>• The working length of MDS is 112 cm and has a constant catheter profile of 18 Fr.<br>• Broadly the MDS may be segregated into five distinct zones from its distal to proximal end.<br>o MyClip Distal Assembly<br>o Catheter<br>o MDS Torque Box<br>o MDS Console-Slider<br>o MDS Console<br>• (as shown in the Figure 08).<br>  <br><br>**Figure 08. MyClip Delivery System (MDS)** |
| MyClip Distal Assembly | • MyClip Distal Assembly comprises of-<br>o Size specific implantable MyClip<br>o MyClip RO (Radiopaque) ring<br>o MDS Metal-slot & Silver aligner marker line<br>o Sandwich RO markers<br>o MyClip Loader<br>• Sizing of implantable MyClip & its technical specification have been described above in Section 7.0 & 8.0 in this document.<br>o The MyClip can be flexed within the left atrium using the knobs located on MDS Torque Box.<br>o Further, the Clip-Arms and Grasper mechanisms can be controlled by using its dedicated Lever system and Rotary Wheel on MDS Console.<br>o Finally, the Clip can be released using the release mechanism on MDS Console. |

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| | • Proximal to the implantable MyClip is the RO (radiopaque) ring which is also echogenic and can be used to identify the distal catheter during procedure simultaneously under fluoroscopy and TEE.<br>• Once the Clip is thoroughly hydrated and de-aired, the Loader is slid over to fully cover the clip prior to insertion within the MGC.<br>• It is recommended to align the MDS Metal-slot along with the proximal Silver aligner marker line to the black aligner marker line on MGC proximal Hub to ensure correct flexion of the distal end of MyClip during the TEER procedure.<br>• Note : It is recommended not to touch the implantable MyClip to prevent inadvertent device malfunctioning/trauma. |
| MDS Catheter | • MDS Catheter is a distally articulating catheter with working length of 112 cm and a constant catheter profile of 18 Fr.<br>• Distally the Catheter has the implantable MyClip, the Loader, the Silver aligner marker line and the two (02) Sandwich RO markers<br>• Proximally the Catheter merges into the MDS Torque Box via the stainless steel MGC Connecting Sleeve. (as shown in the Figure 08)<br>• The distal end of MDS Catheter can be flexed medially via the Medial (M) knob placed on the MDS Torque Box.<br>• Additionally the distal end of MDS Catheter can be flexed anteriorly and posteriorly via the (A) and (P) knob placed on the MDS Torque Box. |
| MDS Torque Box | • Anteriorly (typically facing up), the Torque Box has a bi-directional flexion knob indicating MDS Anterior (A) and MDS Posterior (P) rotations and a flexion free zone indicated by two red dots.<br>• Likewise, laterally (typically facing the Operator), the MDS Torque Box has a bi-directional flexion knob indicating Medial (M) and Lateral (L) movement and a flexion free zone indicated by two red dots.<br>• **Note –** the Lateral (L) movement of the distal MyClip system is not essential during TEER procedure and thus the lateral motion is purposely rendered inactive.<br>• The posterior section (usually the lower part) of the MDS Torque Box has a rectangular mount.<br>• Once the MDS system is Sandwiched (meaning, the MGC distal tip RO marker is fluoroscopically placed between two radiopaque (RO) markers on the distal end of MDS) while in patient's left atrium), it is recommended to securely fix the MDS Torque Box using the Mount within the proximal Angled Mount Arm on the Bracket with the sterile fasteners provided.<br>• Additionally, the proximal part of Torque Box has a flush port for continuous flushing throughout the procedure. (as shown in the Figure 08) |

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| Console Slider | • Console Slider is a shaft proximally fixed to the MDS Torque box and slides within the MDS Console.<br>• The MDS Console position can be fixed on the Console Slider using a Console Bolt.<br>• During the TEER procedure, the Console Slider is frequently used for-<br>o Forward and backward movement of the Clip.<br>o Clockwise and anti-clockwise rotation of the Clip.<br>o Transmitting the torque from proximal to distal tip of the Clip system. |
| MDS Console | • MDS Console is the proximal most unit which houses several key components which allow movement of Graspers, Clip-arms, Clip rotation and release of the implantable MyClip.<br>• Distally a Console-Bolt ensures secure fixation of the MDS Console to the Console Slider.<br>• A flush port is provided on the anterior and posterior part of the Console body for de-airing and continuous flushing during the procedure.<br>• A Grasper-lever (for elevating and lowering the Graspers) and a Clip-Lock-lever (for locking and un-locking the Clip-Arms) are provided on either side of the MDS Console.<br>• A proximally placed Rotary Wheel allows opening and closing of the Clip-Arms at different angles based on the procedural requirements.<br>• A Deployment-Pin wedged between the Rotary Wheel and the Clip-Shaft prevents inadvertent release of the Clip.<br>o The Deployment Knob is placed most proximally which ultimately releases the implantable MyClip from its catheter system. |

| **Section 13.0** | **Additional procedural accessories for TEER procedure** |
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| | Following is the list of important additional STERILE accessories not provided but essential during TEER procedure |
| Introducer sheaths | • Standard 6 Fr, 7Fr, 10Fr – One (01) unit each. |
| Dilators | • 10 Fr, 14 Fr, 18 Fr, 20 Fr, 22 Fr – One (01) unit each. |
| Vascular Closure Device | • Suture based – Two (02) units. |
| Silk sutures | • Size 1.0 – One (01) unit |
| Guide catheter | • Profile 6 Fr – AL1, JR, MP – One (01) unit each. |
| Straight tipped guidewire | • Standard length 0.035” and 0.032” – One (01) unit each. |
| Stiff guidewire 0.035” | • Standard and Exchange length – One (01) unit each. |
| Pig-tail catheter | • Profile – 5 Fr, 6 Fr – One (01) unit each. |
| Transseptal sheath | • Standard curves – 45°, 55°, 90° - One (01) unit each. |
| Transseptal needle | • One (01) unit |
| Normal Saline | • 1000 mL bags – Two (02) units |
| Pressure bags | • 1000 mL – Two (02) units |
| IV Stand with wheels | • One (01) unit |
| High pressure 3-way Stopcocks | • Four (04) units |
| Arterial high-pressure extension tube | • 10 cm – Two (02) units |
| IV tubing | • Sterile Blood infusion IV tubing with thumb-wheel occluder – Two (02) units. |
| Tuohy-Borst with Y-Connector | • Two (02) units |

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| Luer-lock Syringe | • Volume 50 mL – Two (02) units<br>• Volume 20 mL – One (01) unit<br>• Volume 10 mL – One (01) unit |
| Stainless Steel bowl | • Minimum volume 2000 mL – One (01) unit. |
| Artery Forceps | • One (01) unit |
| Scalpel | • One (01) unit |
| Contrast agent | • 50 mL |
| Normal saline | • 2000 mL |
| Standard Heparin | • 5000 IU |
| Heparinised solution | • 100 mL |
| Trolley for device preparation | • Minimum dimension – Length 4.5’ x Breadth 2.5’ – One (01) unit.<br>• With sterile draping. |
| Balloon dilatation catheters | • For septal dilatation<br>o 0.035” guidewire compatible.<br>o Diameters ⌀ ranging – 16 mm, 18 mm, 20 mm |
| ASD closure device | • Diameters ⌀ – 18 mm, 20 mm, 22 mm |
| Additional Emergency Cath-lab equipment & hospital infrastructure in working condition | • Emergency equipment ready in working condition<br>o Heart lung machine<br>o ECMO<br>o Well-equipped Cardiac surgery<br>o Defibrillator (charged and in working condition)<br>• Standard Neurovascular interventional devices<br>o Distal embolic protection<br>o Neuro micro catheters<br>o Clot retrievers<br>o Neuro guide catheters<br>o Embolization coils<br>• Standard Peripheral vascular interventional devices<br>o Covered stent grafts<br>o Cross over sheaths<br>o Peripheral vascular balloons<br>• Cross-matched blood |

| Section 14.0 | **MyClip TEER System – Step-by-step Device Preparation & Functional Inspection** |
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| | • MyClip TEER System and its key accessories must be kept ready in its original packaging prior to the TEER procedure.<br>• Additional key sterile items from Section 13.0 above in this IFU must be kept accessible.<br>• A Trolley (minimum dimension Length 4.5’ x Breadth 2.5’) with sterile drape must be prepared and kept ready.<br>• MyClip TEER System must be prepared by a trained Physician, Nurse or Clinical Application Specialist only.<br>• **Warning :** Failure to adhere to the specified instructions, warnings, and precautions may lead to inadvertent device malfunction, sub-optimal device performance or lead to injury to the patient.<br>• Thoroughly inspect the primary and secondary packaging to ensure product integrity, shelf-life and any physical damage.<br>• **Note :** Discard the device in case there is any abnormality or device damage.<br>• Preparation of the MyClip TEER System involves two key steps :<br>o De-airing, hydration and functional inspection of the MyClip Guide Catheter (MGC).<br>o De-airing, hydration and functional inspection of the MyClip Delivery System (MDS). |

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| Preparation of the MyClip Guide Catheter (MGC) | • Carefully remove the MGC from its sterile packaging using standard aseptic techniques.<br>• Keep a stainless steel bowl filled with 1000 mL Heparinised saline ready.<br>• Place the MGC and its Dilator across the sterile table.<br>• Visually inspect and ensure the MGC and its Dilator are free of any physical damage or abnormalities.<br>• Connect a 10 cm extension tube to the proximally placed Side-Port of MGC Hub.<br>• Connect a Tuohy-Borst Adaptor to the Y-Connector of the MGC Dilator flush port.<br>• Connect a 3-way stop-cock to the Tuohy-Borst side port.<br>• Using a 50 mL syringe with Luer-lock filled with Heparinised saline, de-air and hydrate the MGC Dilator central lumen.<br>• Using wet sterile gauze wipe the Dilator outer surface and hydrate the distal 5-10 cm.<br>• Insert the dilator about 10 cm into the MGC Hub to prime its MGC haemostatic valve and remove.<br>• Using a 50 mL syringe with Luer-lock filled with Heparinised saline, de-air and hydrate the MGC via the 10 cm extension tube previously connected at the Side-Port of MGC Hub.<br>• Raise the MGC distal tip to face upwards while continuous flushing and gently tap along the catheter length to displace/knock off potential air bubbles.<br>• Continue to flush the MGC using 50 mL syringe with Luer-lock filled with Heparinised saline and place an index finger over the distal tip of MGC.<br>• While securely holding the distal tip with index finger, invert the MGC and submerge the tip into a bowl containing 1000 mL of heparinised solution.<br>• Confirm the MGC Hub is holding the saline solution ensuring no air has entered the MGC during this time.<br>• Keep holding the MGC submerged into the heparinized solution until the next step.<br>• Now insert the de-aired and hydrated MGC Dilator into the MGC Hub.<br>• Advance the MGC Dilator into the inverted MGC Hub until its curved tip extends 5 cm distally outside the MGC tip into the Heparinized solution. |

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| | • Maintain the MGC with its Dilator submerged into the Heparinized Solution and perform the functionality inspection as follows-<br>o Rotate the knob on the MGC Hub toward MGC Flex (+) flexion until the distal tip of the guide catheter is flexed to a maximum of 80°.<br>o Now unflex the knob toward neutral zone indicated by two red dots.<br>o Rotate the knob on the MGC Hub towards Negative (-) flexion until the distal tip of the guide catheter is straight.<br>o Now unflex the knob toward neutral zone indicated by two red dots.<br>o Repeat the step one more time to ensure functional distal MGC flexion.<br>o **Warning :** Do not flex the MGC tip beyond 90°.<br>• The MGC is now de-aired, hydrated and ready for use.<br>• Continue to keep the prepared MGC across the sterile zone until further use.<br>• Prior to insertion within femoral vein, rotate the knob on the MGC Hub towards Negative (-) flexion until the distal tip of the guide catheter is straight. |
| Preparation of MyClip Bracket | • Carefully remove the Bracket from its sterile packaging using standard aseptic techniques.<br>• Ensure the three (03) Fasteners are carefully placed on the sterile zone.<br>• Visually inspect and ensure the Bracket and Fasteners are free of any physical damage or abnormalities.<br>• Fix one of the Fasteners at the distal end of Bracket Mount Arm.<br>• Fix the second Fastener at the proximal end of the Angled Mount Arm.<br>• Fix the third Fastener at the proximal residual location of the Angled Mount Arm.<br>• The Bracket is ready for further use.<br>• Continue to keep the prepared Bracket across the sterile zone until further use. |
| Preparation of MyClip Delivery System (MDS) | • Carefully remove the MDS from its sterile packaging using standard aseptic techniques.<br>• Keep a stainless steel bowl with 1000 mL Heparinised saline ready.<br>• Place the MDS across the Sterile table.<br>• Visually inspect and ensure the MDS is free of any physical damage or abnormalities.<br>• Connect a 3-way stop-cock along with High-Pressure IV Set to the Torque Box flush port.<br>• Similarly, connect another 3-way stop-cock along with High-Pressure IV Set to the Console flush port. |

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| | • Now bring the IV-Stand with Wheels close to the Sterile Trolley ensuring that sterility is maintained.<br>• Attach two 1000 mL Heparinized Saline bags on each arm of the IV-Stand and cover individually with two Pressure Bags.<br>• Now individually connect the High-Pressure Tubing of the Torque Box flush port and Console flush port to each Saline Bag.<br>• Set the pressure in each bag to 300 mmHg to initiate the hydration at each flush port.<br>• Holding the MDS Torque Box, slide the MDS Console over the Console Slider shaft repeatedly to de-air & hydrate the shaft thoroughly under continuous flushing.<br>• Heparinized Solution is expected to be filled across the entire MDS catheter length and exit at the distal clip assembly.<br>• Now fill the MDS Console with Heparinized solution to thoroughly de-air and hydrate.<br>• Remove the cap from distally placed MyClip Loader and attach a 3-way Stop-cock to its flush port.<br>• Flush the Loader with Heparinized solution using a 50 mL Syringe with Luer-lock to thoroughly de-air and hydrate.<br>• Carefully slide the Loader filled with Heparinized solution after functional testing of the Clip.<br>• At this time the MDS is de-aired and thoroughly hydrated.<br>• Continuously keep Heparinized solution flushing through the MDS system at both flush ports.<br>• Ensure the protective transparent sleeve over the MyClip Distal Assembly is securely in place to prevent any inadvertent damage to the Clip. |

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| Functional inspection of the MDS Torque Box | • **MDS Anterior (A) and MDS Posterior (P) Knob Flexion**<br>• Rotate the MDS Anterior (A) knob approximately 3/4$^{th}$ turn from the neutral position and visually confirm the distal anterior flexion.<br>  o Now return to neutral position between two red-dots.<br>• Repeat the MDS Anterior (A) knob flexion one more time and return to neutral position.<br>• Rotate the MDS Posterior (P) knob approximately 3/4$^{th}$ turn from the neutral position and visually confirm the distal posterior flexion.<br>  o Now return to neutral position between two red-dots.<br>• Repeat the MDS Posterior (P) knob flexion one more time and return to neutral position.<br><br>• **Medial (M) – Lateral (L) Knob Flexion**<br>• Rotate the Medial (M) knob up to 90° turn from the neutral position and visually confirm the distal medial flexion.<br>  o Now return to neutral position between two red-dots<br>• Repeat the Medial (M) knob flexion one more time and return to neutral position.<br>• **Note –** the Lateral (L) movement of the distal MyClip system is not essential during TEER procedure and thus the lateral motion is purposely rendered inactive. |
| **Functional inspection of the MDS Console** | • **Primary position of the Clip-Arms and Graspers**<br>  o In primary position, the Clip-Arms are locked and open at 120° (away from the central catheter shaft).<br>  o In primary position, the Graspers are locked and lowered (resting on the Clip-Arms). |
| **Unlocking & Locking of Clip-Arms** | • To unlock the Clip-Arms, turn the Clip-Lock-Lever outwards and pull the shaft until the blue line is visible.<br>  o Now the Clip-Arms are unlocked.<br>  o Turn the Clip-Lock-Lever inwards and secure the Clip-Arms at this position.<br>• Now, to lock the Clip-Arms turn the Clip-Lock-Lever outwards and push the Clip-Lock-Lever shaft completely and then turn inwards.<br>  o Now the Clip-Arms are locked.<br>• Repeat the Clip-Arms Un-locking and Locking twice to ensure proper functionality. |

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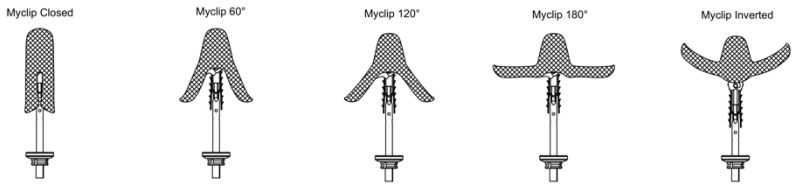
| **Opening and Closing Clip-Arms** | • Using the above steps, un-lock the Clip-Arms<br>• Turn the Rotary Wheel on the proximal MDS Console in Close direction (opposite to arrow) to close the Clip-Arms and visually confirm the position.<br>• Gradually turn the Rotary Wheel in Open direction (towards arrow) to open the Clip-Arms first at 60° followed by 120° and then at 180° and visually confirm these positions.<br>• Continue to turn the Rotary Wheel in Open direction (not more than one (01) full turn) till the Clip-Arms are reversed and visually confirm the position.<br>• Now, gradually turn the Rotary Wheel in Close direction (opposite to the arrow) to close the Clip-Arms start from reversed to 180° to 120° to 60° to fully closed position till the resistance is felt. (as shown in Figure 09.)<br>• Lock the Clip-Arms using above described steps.<br>  <br>**Figure 09. MyClip Arm Positions at Different Angles** |
| **Elevating and Lowering the Graspers** | • Using the above mentioned steps, un-lock the Clip-Arms to 120°.<br>• To elevate the Graspers, turn the Grasper-Lever outwards and pull the shaft until the blue line is visible.<br>  o Now the Graspers are elevated and unlocked.<br>  o Turn the Grasper-Lever inwards to lock and secure the elevated position.<br>• To lower the Graspers, turn the Grasper-Lever outwards and push its shaft completely and then turn the lever inwards.<br>  o Now the Graspers are lowered again and locked in position.<br>• Repeat the Grasper Elevation and Lowering twice with Clip-Arms at 120° to ensure proper functionality of the Graspers and visually confirm.<br>• Now both the Clip-Arms and Grasper functionality have been confirmed.<br>• Proceed to lower the Graspers and close the Clip-Arms fully for next steps.<br>• Ensure, continuous Heparinized solution is flushed all through the above steps. |

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| Loading the MyClip | • Release the Console Bolt and turn the Console anti-clockwise with simultaneous forward and backward movement of the Console over the Console Slider shaft.<br>• Now, turn the Console clockwise with simultaneous forward and backward movement of the Console over the Console Slider shaft.<br>• Repeat this 2-3 times.<br>• Retract the Console handle completely and fix the Console Bolt securely.<br>• With the Clip-Arms (and the Graspers) in fully closed position and the transparent sleeve still intact, slide the MyClip Loader gently over the MyClip without touching the Clip-Arms.<br>• Firmly hold the distal part of transparent sleeve and fully remove the sleeve with a single sharp tug and discard the sleeve.<br>• At this time, the MyClip Delivery System (MDS) has been fully inspected for its functionality; it is de-aired and thoroughly hydrated and ready to be used. |

| **Section 15.0** | **Setting up the Cath-lab and Preparation of Patient for Mitral TEER Procedure** |
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| Setting up the Cath-Lab | • Set up the Cath-lab as per standard hospital practice with 3D TEE support under general anaesthesia for left heart interventional procedures such as Transseptal procedures, TMVR, mitral TEER, left atrial appendage closure etc.<br>• Arrange the standard anaesthesia equipment at the patient head side with experienced anaesthetist proficient in general anaesthesia in patients with heart failure conditions.<br>• Ensure proper advanced TEE machine 3D capabilities and also keep the TTE probe ready staffed with experienced Echocardiography personnel.<br>• It is preferable to mirror the 3D TEE image on the Cath-lab monitors (slave imaging) for Primary operators to perform the mitral TEER under simultaneous TEE and Fluoroscopic imaging.<br>• Ensure routine hemodynamic equipment in working condition.<br>• Arrange for a large Sterile Trolley for MyClip TEER System preparation as per the list provided in Section 13.0 of this document.<br>• Arrange for all other key accessories which are not provided with MyClip TEER System but are essential for mitral TEER procedure as per Section 13.0 of this document.<br>• Ensure availability of trained Cath-lab personnel during mitral TEER procedure such as-<br>o Cath-lab scrub nurses<br>o Radiographers (Cath-Technicians)<br>o Circulating nurses<br>o Clinical Application Specialist well trained in MyClip TEER System preparation and with mitral TEER procedures<br>• Ensure availability of cardio thoracic and vascular surgeon on stand-by for any unanticipated complication management.<br>• Ensure availability of cardiac critical unit and trained intensivist for post procedure medical management. |
| **Patient preparation for mitral TEER procedure** | • Prepare the patient for general anaesthesia as per standard hospital practice for Transseptal catheterization.<br>• Foley's bladder emptying catheter will be required in place.<br>• Measure 80 cm distance from the Patient's mid-sternum region toward the index knee.<br>• Place the Ground-Plate with Meril logo facing up below the patient's index leg roughly below the knee zone.<br>• Position the Podium on the Ground-Plate with its legs across the Patient's index leg such that the distal edge (towards patient's heart) of the Podium is at 80 cm from the mid-sternum region.<br>• Adjust the Podium slant using the buttons on telescopic fore-legs. |

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| | • Ensure the hind-legs of the Podium is slightly elevated as compared to its fore-legs.<br>• Proceed with the venous access site preparation as per standard hospital practice.<br>• Fully cover the patient with sterile drapes ensuring the Podium is beneath the sterile drape.<br>• Additional contralateral femoral vein may be accessed for continuous invasive left atrial (LA) pressure monitoring.<br>• Other arterial access may be kept ready for any anticipatory coronary procedure.<br>• Patient will be heparinized during the procedure to maintain ACT of > 250 secs. |

| **Section 16.0** | **Step-by-Step Mitral TEER Procedure with MyClip TEER System** |
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| Step-by-step mitral TEER procedure | The transcatheter edge to edge repair (TEER) of mitral valve procedure may be broadly split into five (05) phases-<br>1. Vascular access & Transseptal puncture (TSP).<br>2. Advancement of MyClip Guide Catheter (MGC) in left atrium (LA).<br>3. Advancement of MyClip Delivery System (MDS) into left atrium (LA) and MyClip orientation over the mitral valve.<br>4. Advancing MyClip into LV, mitral valve leaflet grasping, MR/ hemodynamic assessment, MyClip withdrawal and repositioning.<br>5. Release of implantable MyClip, MR/ hemodynamic assessment, decision for additional clip & vascular closure. |
| **Standard TEE views** | **Following are the standard recommended 2D/3D TEE views for successful mitral TEER procedure.**<br>**Warning :** Inability to acquire standard 2D/3D TEE views may hamper the procedural and final clinical outcomes. |
| Transseptal Puncture (TSP) | • Mid-oesophageal Bi-caval view (~90° to 110°)<br>o Identifies fossa ovalis (FO) and guides puncture location (Mid-posterior to achieve ideal distance between septal puncture and mitral annulus).<br>• Mid-oesophageal short axis at base (~25° to 45°)<br>o Confirms anterior-posterior position of the transseptal needle.<br>• Mid-oesophageal four chamber view (0° to 10°)<br>o To assess the height from puncture site to the mitral valve (for FMR 3.5 to 4.0 mm; for DMR 4.0 to 4.5 mm). |
| Working views during TEER | • Mid-oesophageal Inter-commissural or Bi-commissural view (~60°) < > x-plane to LVOT view<br>o Visualizes A2-P2 alignment and Clip trajectory.<br>• 3D En Face View<br>o Confirms Clip orientation over target scallops (A2-P2 most common).<br>• Mid-Oesophageal Long-Axis View (~120° to 150°) < > x-plane to Bi-commissural view<br>o Confirms leaflet insertion into the Clip-Arms during grasping.<br>• Trans gastric Short-Axis View (~0–40°)<br>o Evaluates residual MR jets, leaflet motion, and Clip orientation. |

| **Phase 1.0** | **Vascular Access & Transseptal Puncture (TSP)** |
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| Vascular access | • Ultrasound guided common femoral vein (CFV) access is recommended during TEER procedure<br>o Identify the anatomical landmarks under ultrasound guidance to perform superficial and deep local anaesthesia.<br>o Under ultrasound guidance use a front walled needle (18 gauge) with or without a syringe to access the CFV<br>o Introduce a short 0.035" J-curve guidewire into the CFV.<br>o Confirm the guidewire position via Ultrasound.<br>o Exchange a 9 Fr short Introducer sheath into the CFV.<br>o Partial heparinization must be initiated at this time.<br>o Pre-close with a suture based vascular closure device at this time.<br>o Vascular access is now complete. |
| Transseptal Puncture (TSP) | • Introduce a standard length 0.032" J-tip guidewire under fluoroscopic guidance<br>• **Warning :** Follow standard protocols in case the patient has pacemaker electrodes to prevent guidewire entrapment.<br>• Under fluoroscopic guidance, advance the guidewire from inferior vena cava (IVC) toward right atrium (RA) and then into the superior vena cava (SVC).<br>• Introduce the TSP over the guidewire under fluoroscopic guidance and confirm the TSP position via TEE in Bi-caval view till the TSP tip is 3-4 cm superior to the cavo-atrial junction.<br>• Remove the guidewire while keeping the TSP tip facing left in the fluoroscopic AP view.<br>• Now, gently advance the TSP needle inside the sheath under fluoroscopic guidance until it reaches the sheath tip.<br>• **Warning :** To avoid perforations, ensure the needle is 4 cm away from the sheath tip.<br>• Under fluoroscopic and TEE guidance (Bi-Caval view x-plane to short axis) slowly pull back the TSP system in the RA (simultaneously holding both the needle and the sheath with its dilator).<br>• Monitor the tenting as the TSP dilator tip falls into the fossa ovalis (FO).<br>• Now turn the TSP clockwise to move the tip posteriorly.<br>• Manoeuvre the tip position to confirmed at middle of FO in Bi-caval and posteriorly in short axis at base.<br>• Now measure the height of the tenting from mitral valve annular plane (for FMR 3.5 to 4.0 mm; for DMR 4.0 to 4.5 mm)<br>o It is recommended to draw two lines in parallel – one extending from the tenting and the other at mitral annular plane and then draw a perpendicular line to measure the height. |

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| | • Once the optimal transseptal tenting and height of tenting is confirmed, return to TEE Short-axis view and prepare for transseptal puncture.<br>• **Note :** Alternately, diathermy surgical system based or RF based TSP may be done.<br>• Under constant TEE and fluoroscopic guidance, carefully advance the needle beyond the dilator applying steady forward pressure to puncture the intra-atrial septum and enter LA.<br>• **Note :** The tenting at FO is released as soon as TSP is achieved.<br>• **Warning :** Ensure the TSP needle is away from LA wall and the aorta at all times and verify absence of any pericardial effusion at this time using TEE.<br>• Remove the TSP dilator and the needle safely.<br>• Introduce one standard length, 0.032" J-tip guidewire along with one super stiff, exchange length, 0.035" guidewire into the LA via the TSP sheath.<br>• Exchange a 4-5 Fr pigtail over the 0.032" J-tip guidewire and park in LA for peri-procedural LA pressure monitoring.<br>• Under fluoroscopy and TEE guidance short axis view, park the 0.035" super stiff into the left upper pulmonary vein using a 4-5 Fr multi-purpose guide catheter.<br>• Remove the TSP Sheath and using manual compression at the access site maintain haemostasis while preparing to introduce the MyClip Guide Catheter (MGC).<br>• **Caution :** Check ACT at this time and consider additional dose of Heparin to maintain ACT > 250 secs.<br>• TSP procedure is complete now. |

| Phase 2.0 | Advancement of MyClip Guide Catheter (MGC) in left atrium (LA) |
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| | • Preparation – de-airing, thorough hydration & functional inspection of the MGC has been described in detail in Section 14.0 in this document.<br>• Connect a 50 mL syringe partially filled with normal saline to the proximal MGC flush port. |
| | • Prepare the skin for large bore introducer sheath insertion and sequentially prime the CFV using step up dilators starting from 14 Fr, 18 Fr, 20 Fr and 22 Fr.<br>• Keep manual compression at all times to ensure haemostasis during the step dilatation.<br>• Using the Negative (-) knob on the MGC-Hub straighten the distal tip as much as possible.<br>• Load the MGC-Dilator and advance the MGC system on the exchange length super stiff 0.035” guidewire previously parked in the left upper pulmonary vein.<br>• Bring the MGC Flex (+) / MGC Straight (-) Knob on the MGC Hub to neutral position (between two red-dots) to reinstate the natural curve of MGC distal end.<br>• Under constant fluoroscopy and TEE (short axis view), cross the inter-atrial septum.<br>• Once the MGC distal RO tip is confirmed in the LA via TEE (short axis, multi-plane and 3D En Face views), withdraw the Dilator within the MGC.<br>• Withdraw the exchange length super stiff 0.035” guidewire into the Dilator.<br>• Confirm by TEE (short axis and 3D En Face views) that the distal MGC tip is approximately 1.5 to 2 cm inside LA.<br>• Now, simultaneously pull the Dilator along with Guidewire out from the MGC Hub slowly while continuously aspirating to ensure no external air embolizes into the MGC.<br>• Bright red arterial blood is expected to be aspirated as the Dilator and Guidewire exits the MGC proximal haemostatic valve.<br>• Keep a thumb at the MGC proximal haemostatic valve to prevent any air from entering the MGC.<br>• **Note :** Continuously watch under TEE to ensure the MGC Tip is not abutting the LA wall, aorta or any other intra-cardiac structure.<br>• The aspirated blood from Flush port syringe may be re-infused back into the patient via central line.<br>• Securely hold the MGC in this position until it is fixed on the Bracket.<br>• Place the Anti-Skid Silicone Mat over the Podium using sterile, aseptic technique with Meril logo facing up.<br>• Place the MyClip Bracket over the Anti-Skid Silicone Mat using sterile, aseptic technique with Meril logo facing up. |

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| | • Securely fasten the MGC Hub at its Stainless Steel MGC Connecting Sleeve to distal Mounting Arm of the Bracket.<br>• Once again ensure MGC Tip is freely within the LA by manually moving the MGC Hub in Anterior (A) / Posterior (P) direction under TEE guidance (short axis, multi-plane and 3D En Face views).<br>• Connect the Pressure line to the Pig-Tail catheter placed in LA for continuous LA pressure monitoring.<br>• MGC Placement procedure is now complete. |

| Phase 3.0 | **Advancement of MyClip Delivery System (MDS) into Left Atrium (LA) and MyClip Orientation Over the Mitral Valve** |
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| | • Preparation – de-airing, thorough hydration & functional inspection of the MDS has been described in detail in Section 14.0 in this document.<br>• Bring the MDS System to the Operating Table maintaining aseptic conditions.<br>• Simultaneously bring the IV Stand with wheels towards the contralateral side of Operating Table carefully ensuring both the tubing are not entangled or stretched maintaining aseptic condition.<br>• Insert the Loader with MyClip Distal Assembly into the MGC Haemostatic Valve under continuous jet of saline to prevent inadvertent air entrapment and subsequent embolization during MDS insertion.<br>• Match the Silver aligner marker line on the MDS with the Black aligner marker line on the MGC Haemostatic Valve to ensure correct flexion of the MDS in LA and advance the MDS up to the tip of MGC under TEE (short axis view) and fluoroscopic guidance. |
| | • **Caution :** Carefully advance the MDS into the LA under constant TEE (short axis at base view) guidance ensuring the Clip is not abutting against LA walls, aorta or any intra-cardiac structures.<br>• Under active TEE (short axis at base view) & fluoroscopic guidance, simultaneously withdraw the MGC (ensuring its distal tip remains in LA at all times) and advance the MDS till the MGC tip RO marker is Sandwiched between the two RO markers on MDS.<br>• **Note :** Use Anterior (A) / Posterior (P) rotation on the MGC Hub to facilitate manoeuvring during the Sandwiching process.<br>• Sandwiching ensures optimal manoeuvring and flexion of MDS within the LA.<br>• At this point MyClip is expected to be positioned towards the pulmonary veins (this can be ascertained under TEE guidance).<br>• Under TEE guidance (short axis at base view), carefully rotate the Medial (M) knob on the MDS-Torque Box avoiding interaction with LA structures such as Coumadin Ridge and the Left Atrial Appendage (LAA).<br>• At this time, transition the view on TEE from Short Axis at Base to Bi-commissural View.<br>• Ensure the MyClip is positioned on the mitral valve.<br>• **Note :** The MDS Catheter tends to ride up by application of the Medial (M) knob to expose the inner Clip shaft. Correct this phenomenon by releasing the MDS Console-Bolt and retracting the MDS-Console handle completely. Once done, re-secure the MDS Console-Bolt. |

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| | • Under TEE guidance (bi-plane view : Bi-commissural and LVOT views) position the Clip medio-laterally at the centre and the antero-posteriorly at the centre of the mitral valve using the Medial (M) knob on MDS-Torque Box and Anterior (A) / Posterior (P) movements of the MGC Hub.<br>• Under TEE guidance (Bi-commissural views) ensure the Clip trajectory is toward the apex of the heart by releasing the MDS-Console Bolt and forward-backward movement of Console Slider ensuring at no point the MyClip touches the mitral valve.<br>• **Note :** The trajectory is not biased medio-laterally.<br>• Now, open the Clip-Arms as described in Section 14.0 in this document at 120° and check the orientation of the Clip-Arms under TEE guidance (3D En Face view).<br>• Ensure the Clip-Arms are perpendicular to the mitral valve coaptation line (typically 12-6 o'Clock when the Aorta is positioned at 12-o'Clock).<br>• Correct the Clip-Arm orientation under TEE guidance (3D En Face view) by releasing the MDS-Console Bolt and rotating the Console handle clockwise or anti-clockwise ensuring rotation is not more than 5° each time and transmit the residual torque in MDS Catheter by controlled back-and-forth Console Slider movement until the desired orientation is achieved.<br>• Under TEE guidance (bi-plane : Bi-Commissural and LVOT views) add colour doppler and ensure the MyClip is bisecting the MR jet.<br>• **Note :** If the Clip is not bisecting the MR jet, hold the Bracket base firmly and advance the entire system to shift the Clip laterally or retract to shift medially across the mitral valve. Continue fine-tuning the Clip position in this manner until the MR jet is clearly bisected on colour Doppler.<br>• At this point remove the parallax from the Clip fluoroscopically by adjusting the C-arm angle. Note the new C-arm angle and retain a reference image for future purpose. This will help to identify change in Clip arm orientation fluoroscopically.<br>• Under TEE guidance (Bi-plane : Bi-commissural and LVOT views) close the Clip to 60°.<br>• At this point the MyClip system is ready to be advanced into the left ventricle (LV). |

| Phase 4.0 | **Advancing MyClip into LV, Mitral Valve Leaflet Grasping, MR/ Hemodynamic Assessment, MyClip Withdrawal and Repositioning** |
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| | • Release the Console Bolt, stabilise the Console and gradually advance the Console handle under TEE guidance (Bi-plane : Bi-commissural and LVOT views), without altering the Clip orientation to introduce the MyClip into the LV.<br>• Stop further advancement as soon as the MyClip RO (radiopaque) ring is seen just below the free edge of the mitral valve leaflets.<br>• Secure the Console Bolt and proceed to open the Clip-Arms to 120°.<br>• Under TEE guidance (3D En Face view) reassess if the Clip orientation is perpendicular to the mitral valve coaptation line and still bisecting the MR jet.<br>• **Note :** In case the Clip has changed its trajectory medially during transition into the LV, reduction in medial flexion using the Medial (M) knob and/or lateral shift of the entire system under TEE guidance (Bi-plane : Bi-commissural and LVOT views) will ensure correct the Clip trajectory.<br>• **Caution :** The above manoeuvre should be exercised only for minor adjustments. In case of major adjustments, it is recommended to withdraw the Clip back into LA after reversing the Clip-Arms completely and reorient the Clip while in LA.<br>• Under TEE guidance (Bi-plane : Bi-commissural and LVOT views) reassess the position of Clip to ascertain that it is still bisecting the MR jet in Bi-commissural view and LVOT view.<br>• Release the Console Bolt and start retracting the Clip till the leaflets are resting inside the Clip-Arms and the free edge of the mitral valve leaflets are at the base of the Clip-Arms.<br>• **Note :** Adjustment of Anterior (A) / Posterior (P) rotation of MGC Hub may be used to ensure both the leaflets are resting well inside the Clip-Arms and the free edge of the mitral valve leaflets are at the base of the Clip-Arms.<br>• Proceed to lower the Graspers using technique described in Section 14.0 above in this document.<br>• **Note :** Under TEE guidance in LVOT view, ascertain if both the Graspers are gently bouncing with the mitral valve leaflet motion. Further optimisation of TEE view may be considered to fully appreciate the leaflet grasping.<br>• Close the Clip-Arms to 60° and lock the Clip as described in Section 14.0 above in this document.<br>• Ensure the adequate leaflet grasping under TEE guidance in Four-chamber, LVOT, Bi-Commissural and 3D-En Face views.<br>• Add colour doppler in Bi-Commissural view to assess reduction in MR. |

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| | • Close the Clip-Arms completely if MR reduction is satisfactory.<br>• **Note :** While closing the Clip, release the Console Bolt and advance the Console Handle 1 mm to reduce the stretching of chordae and secure the Console Bolt in its new location.<br>• Ensure the adequate leaflet grasping under TEE guidance in Four-chamber, LVOT, Bi-Commissural and 3D-En Face views.<br>• Add colour doppler in Bi-Commissural view to assess reduction in MR.<br>• Assess the mitral valve hemodynamic by measuring the valve gradients, pulmonary vein flow, LA pressure and V-wave.<br>• The MyClip is now ready to be deployed if all TEE and hemodynamic assessment readings are satisfactory.<br>• **Note :** If the reduction in MR and hemodynamic assessment is suboptimal, reposition the Clip by repeating the above mentioned steps. |

| Phase 5.0 | **Release of Implantable MyClip, MR/Hemodynamic Assessment, Decision for Additional Clip & Vascular Closure.** |
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| | • At this point the Rotary Wheel on Console-Handle is completely in closed position.<br>• Bring the Rotary Wheel to neutral position by rotation toward Open position (towards the arrow).<br>• Free movement of the Rotary Wheel indicates neutral position.<br>• Make one full rotation of the Rotary Wheel towards Open position and confirm on fluoroscopy that the Clip-Arms do not open beyond 10°.<br>• Increase the flush till Heparinized solution is seen flowing through the Graspers and Clip-Lock-Levers.<br>• Open the Grasper-Lever Cap and remove the sealing-ring.<br>• Unwind the Grasper Nitinol wires and floss to ensure free movement.<br>• Open the Clip-Lock-Lever Cap and remove the sealing ring.<br>• Unwind the Clip-Lock-Lever Nylon Suture and cut through the protective sleeve of one of the two Sutures, remove the Sleeve and discard.<br>• Pull the other end of the second Suture in one continuous motion till it is completely extracted from the MDS system.<br>• Rotate the Rotary Wheel in Open direction one full turn. The Clip-Arms must remain locked. Confirm this on fluoroscopy.<br>• Pull the secure Clip-Release Deployment Pin wedged proximally.<br>• Turn the Rotary Wheel in Open direction till the grooves on proximal shaft are clearly visible.<br>• Now turn the Final Deployment Knob full eight (08) rotations in Open direction (towards arrow).<br>• Cut one of the two Grasper Nitinol wires and pull the remaining wire in one continuous motion till it is completely extracted from the MDS system.<br>• Rotate the Final Deployment Knob one full turn, and release the Console Bolt.<br>• Pull the Final Deployment Knob not more than 1 cm and pull the Console Handle to detach the Clip from its shaft.<br>• Perform all the above steps fluoroscopically and save all images.<br>• Remove all the flexion applied during the procedure to all the Knobs to ensure atraumatic withdrawal of the MDS Catheter Shaft from LA into the MGC.<br>• Pull the MDS Catheter out from the MGC till the proximal Sandwich RO marker is outside the MDS-Loader.<br>• Pull the Loader outside from the MGC Haemostatic Valve.<br>• Under TEE guidance assess the MR reduction and if satisfactory proceed to remove the MGC by pulling the system from LA followed by vascular closure of access site. |

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| | • In case, the MR reduction is not optimal or satisfactory, select the second Clip size and follow the same steps described previous in Section 16.0, Phase 3.0 to 5.0.<br>• **Caution :** Use Negative (-) knob on MGC Hub and straighten the tip of MGC while pulling the MGC from RA towards IVC.<br>• Close the Vascular Access site securing the vascular closure device inserted at the beginning.<br>• Optionally vascular access can be closed by traditional Figure-of-8 technique using a standard 1.0 or 2.0 Silk suture.<br>• The TEER procedure with MyClip TEER System is now complete. |

| Section 17.0 | Glossary of Key Terms and Abbreviations |
|---|---|
| MR | Mitral regurgitation |
| FMR | Functional or secondary mitral valve regurgitation |
| DMR | Degenerative mitral valve regurgitation |
| MGC | MyClip Guide Catheter |
| MDS | MyClip Delivery System |
| MGC Hub | Proximal Hub on MyClip Guide Catheter which allows MGC Flex (+) and MGC Straight (-) flexion as well as MGC Anterior (A) and MGC Posterior (P) rotation |
| MDS Torque Box | Placed on the MyClip Delivery System and has two flexion knobs. One on the top surface which allows MDS Anterior (A) and MDS Posterior (P) rotation of distal tip and one on the side which allows Medial (M) rotation of the distal tip |
| MDS Console | The proximal system on MDS which has Clip-Lock-Lever and Grasper-Lever; Rotary Wheel, MyClip release mechanisms |
| RO marker | Radiopaque marker |
| TSP | Transseptal Puncture |
| CFV | Common Femoral Vein |
| TEE | Transesophageal Echocardiography |
| TTE | Transthoracic Echocardiography |
| RA | Right Atrium |
| LA | Left Atrium |
| IVC | Inferior Vena Cava |
| SVC | Superior Vena Cava |
| FO | Fossa Ovalis |

| Section 18.0 | Symbols Used in Product Labelling |
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|  | Medical Device |
|  | Keep dry. Protect from moisture |
|  | Keep away from sunlight |
|  | Sterilized using ethylene oxide |
|  | Consult instructions for use (IFU) or consult electronic instructions for use (e-IFU) |
|  | Do not reuse |
|  | Do not resterilize |
|  | Non pyrogenic |
|  | Do not use if the packaging is damaged and consult IFU |
|  | Caution |
|  | Manufactured in India |
|  | MR conditional |
|  | Date of manufacture |
|  | Batch code |
|  | Catalogue number |