

### MITRACLIP G4 SYSTEM

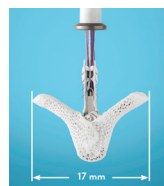
PRODUCT CODE	DESCRIPTION	PIECE COUNT
MC0707-NT	<b>MitraClip G4 NT bundle</b> [Contents: one (1) CDS0707-NT, one (1) SGC0707]	2
MC0707-XT	<b>MitraClip G4 XT bundle</b> [Contents: one (1) CDS0707-XT, one (1) SGC0707]	2
MC0707-NTW	<b>MitraClip G4 NTW bundle</b> [Contents: one (1) CDS0707-NTW, one (1) SGC0707]	2
MC0707-XTW	<b>MitraClip G4 XTW bundle</b> [Contents: one (1) CDS0707-XTW, one (1) SGC0707]	2
CDS0707-NT	<b>MitraClip G4 NT Clip Delivery System</b>	1
CDS0707-XT	<b>MitraClip G4 XT Clip Delivery System</b>	1
CDS0707-NTW	<b>MitraClip G4 NTW Clip Delivery System</b>	1
CDS0707-XTW	<b>MitraClip G4 XTW Clip Delivery System</b>	1
SGC0707	<b>MitraClip G4 Steerable Guide Catheters</b>	1



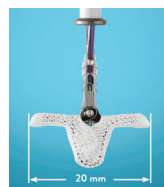
### MITRACLIP G4 SYSTEM DIMENSIONS

COMPONENT	DIMENSION			
DELIVERY CATHETER				
Extended Length (from Sleeve curved at 90 degrees)	> 65 mm			
STEERABLE SLEEVE				
Working Length Catheter	109.5 cm			
Distal Shaft Outer Diameter	5.3 mm (16 Fr)			
MITRACLIP™ G4 IMPLANT				
	G4 NT	G4 NTW	G4 XT	G4 XTW
Grasping Width at 120 degrees (Figure 1A, Figure 2A)	17 mm minimum		22 mm minimum	
Clip Width at 180 degrees (Figure 1B and 2B)	20 mm nominal		25 mm nominal	
Arm Width (Figures 1D and 2D, Figures 1E and 2E)	4 mm maximum	6 mm maximum	4 mm maximum	6 mm maximum
Arm Length (Coaptation Length) (Figure 1C, Figure 2C)	9 mm maximum		12 mm maximum	
STEERABLE GUIDE CATHETER				
Working Length	80.0 cm			
Catheter Proximal Shaft Outer Diameter	8.4 mm (25 Fr)			
Catheter Distal Shaft / Tip Outer Diameter (Septal Crossing)	7.7 mm (23 Fr)			
DILATOR				
Working Length	122.0 cm			
Shaft Inner Diameter	1.0 mm (3 Fr)			
Shaft Outer Diameter	5.4 mm (16 Fr)			
Distal Tip Outer Diameter	1.5 mm (4 Fr)			

#### MITRACLIP G4 NT AND NTW IMPLANT DIMENSIONS:



**FIGURE 1A**  
Grasping Width at 120 degrees



**FIGURE 1B**  
Clip Width at 180 degrees



**FIGURE 1C**  
Arm Length

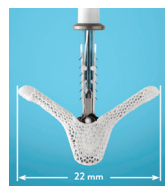


**FIGURE 1D**  
NT Arm Width

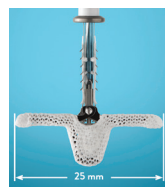


**FIGURE 1E**  
NTW Arm Width

#### MITRACLIP G4 XT AND XTW IMPLANT DIMENSIONS:



**FIGURE 2A**  
Grasping Width at 120 degrees



**FIGURE 2B**  
Clip Width at 180 degrees



**FIGURE 2C**  
Arm Length



**FIGURE 2D**  
XT Arm Width



**FIGURE 2E**  
XTW Arm Width

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY.**

Always check the regulatory status of the device in your region.

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REQUIRED ACCESSORIES

PRODUCT CODE	DESCRIPTION	PIECE COUNT
SZR01ST	Stabilizer	1
LFT01ST	Lift	1
PLT01ST	Support Plate	1



One (1) Silicone Pad, three (3) Fasteners (All are included sterile with the Steerable Guide Catheter)

HOW SUPPLIED

Contents:

Clip Delivery System contents:

- One (1) Clip Delivery System with the MitraClip G4 Implant, one (1) MitraClip Implant Card

Steerable Guide Catheter contents:

- One (1) Steerable Guide Catheter, one (1) Dilator, one (1) Silicone Pad, three (3) Fasteners

Sterile:

The Clip Delivery System and Steerable Guide Catheter are sterilized with ethylene oxide gas and provided in a thermoformed tray with lid, in a sealed pouch. Parts of the devices that are in either direct or indirect contact with circulating blood are non-pyrogenic. Note the product “Use By” date specified on the package. DO NOT use if the “Use by” date has passed. These devices are intended for single-use only. Do not reuse. Do not resterilize.

This single use device cannot be reused on another patient, as it is not designed to perform as intended after the first usage. Changes in mechanical, physical, and / or chemical characteristics introduced under conditions of repeated use, cleaning, and / or resterilization may compromise the integrity of the design and / or materials, leading to contamination due to narrow gaps and / or spaces and diminished safety and / or performance of the device. Absence of original labeling may lead to misuse and eliminate traceability. Absence of original packaging may lead to device damage, loss of sterility, and risk of injury to the patient and / or user. Inspect all product prior to use. Do not use if the package is open or damaged, or if product is damaged. Do not reinsert the CDS or Clip after single use in patient.

The white Guide tip shape retainer and transparent protective tubing are provided sterile and preinstalled on the distal tip of the Steerable Guide Catheter. The Fasteners and the Silicone Pad used

ADDITIONAL REQUIRED EQUIPMENT NOT INCLUDED

- Transseptal sheath and guidewire Transseptal needle
- Step-up dilators
- 260 cm of 0.9 mm (0.035”) super stiff exchange length guidewire
- High pressure three way stopcocks (5)
- Arterial high pressure extension tubing (3)
- 50-60 cc syringes with luer fitting (2)
- 1000 ml pressure bags (2)
- Sterile IV tubing with thumbwheel occluders (2)
- Heparinized sterile saline solution (2) 1 liter bags
- Rolling IV Pole
- Sterile Basin

with the Stabilizer are provided sterile with the Steerable Guide Catheter. The Dilator, Fasteners and the Silicone Pad are intended for single use only. Do not reuse. Do not resterilize, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

Non-sterile:

**CAUTION: The Stabilizer, Support Plate and Lift are provided non-sterile. Follow the cleaning and sterilization instructions provided with the Stabilizer, Support Plate and Lift.**

Storage:

Handle with care. Store in original packaging. Keep dry. Keep away from sunlight.

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that the MitraClip G4 Implants are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3.0 T)
- Maximum spatial field gradient of 4,000 Gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).

Under the scan conditions defined above, MitraClip G4 Implants are expected to produce a maximum temperature rise of less than or equal to 3.1°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by a pair of MitraClip Implants extends approximately 40 mm beyond the MitraClip G4 Implants when imaged with a spin echo or gradient echo pulse sequence in a 3 T magnetic resonance imaging system. The presence of additional implants in a patient’s valve may increase the image artifact size when imaged in an MRI system.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at [eifu.abbottvascular.com](http://eifu.abbottvascular.com) or at [medical.abbott/manuals](http://medical.abbott/manuals) for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. Information contained herein for **DISTRIBUTION outside of the U.S. ONLY**. Always check the regulatory status of the device in your region.

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