

MitraClip™ and TriClip™

ACCESSORIES



en ENGLISH	da DANSK	ro ROMÂNĂ	hr HRVATSKI
de DEUTSCH	el ΕΛΛΗΝΙΚΑ	ru РУССКИЙ	sr SRPSKI
fr FRANÇAIS	pl POLSKI	fi SUOMI	mk МАКЕДОНИЈА
es ESPAÑOL	hu MAGYAR	no NORSK	uk УКРАЇНСЬКА
it ITALIANO	cs ČESKY	et EESTI KEEL	id INDONESIA
pt PORTUGUÊS	tr TÜRKÇE	lv LATVIEŠU	vi TIẾNG VIỆT
sv SVENSKA	sk SLOVENSKY	lt LIETUVIŲ	ar العربية
nl NEDERLANDS	bg БЪЛГАРСКИ	sl SLOVENŠČINA	

GRAPHICAL SYMBOLS FOR MEDICAL DEVICE LABELING: SOURCE REFERENCE FOR RECOGNIZED SYMBOLS RETAINED AT THE MANUFACTURER IN THE MEDICAL DEVICE FILE; GRAFISCHE SYMBOLE ZUR BESCHRIFTUNG VON MEDIZINPRODUKTEN: QUELLREFERENZDOKUMENT FÜR ANERKANNTE SYMBOLE LIEGT BEIM HERSTELLER IN DER MEDIZINPRODUKTDATEI VOR; SYMBOLES GRAPHIQUES POUR L'ÉTIQUETAGE DES DISPOSITIFS MÉDICAUX : LES RÉFÉRENCES SOURCES POUR LES SYMBOLES RECONNUS SONT CONSERVÉES CHEZ LE FABRICANT DANS LE DOSSIER DES DISPOSITIFS MÉDICAUX ; SÍMBOLOS GRÁFICOS UTILIZADOS EN EL ETIQUETADO DE PRODUCTOS SANITARIOS: LA REFERENCIA ORIGINAL PARA LOS SÍMBOLOS RECONOCIDOS LA GUARDA EL FABRICANTE EN SU ARCHIVO DE PRODUCTOS SANITARIOS; SIMBOLI GRAFICI PER L'ETICHETTATURA DI DISPOSITIVI MEDICALI: FARE RIFERIMENTO AL TESTO SORGENTE PER I SIMBOLI RICONOSCIUTI CONSERVATI PRESSO IL PRODUTTORE NEL FILE DISPOSITIVI MEDICALI; SÍMBOLOS GRÁFICOS PARA ROTULAGEM DE DISPOSITIVOS MÉDICOS: REFERÊNCIA DE FONTE PARA SÍMBOLOS RECONHECIDOS RETIDOS PELO FABRICANTE NO FICHEIRO DO DISPOSITIVO MÉDICO; GRAFISKA SYMBOLER FÖR MÄRKNING AV MEDICINSK UTRUSTNING: KÄLLREFERENS FÖR ERKÄNDA SYMBOLER SOM FINNS KVAR HOS TILLVERKAREN I FILEN FÖR MEDICINSK UTRUSTNING; GRAFISCHE SYMBOLEN VOOR DE ETIKETTERING VAN MEDISCHE HULPMIDDELEN: BRONVERMELDING VOOR ERKENDE SYMBOLEN WORDT DOOR DE FABRIKANT BEWAARD IN HET DOSSIER VAN HET MEDISCH HULPMIDDEL; GRAFISCHE SYMBOLER FOR MÆRKNING AF MEDICINSK PRODUKT: KILDEHENVISNINGER TIL ANERKENDTE SYMBOLER OPBEVARES HOS PRODUCENTEN I FILEN VEDRØRENDE DET MEDICINSKE PRODUKT; ГРАФИКА СΥΜΒΟΛΑ ΓΙΑ ΤΗ ΣΗΜΑΝΣΗ ΙΑΤΡΙΚΩΝ ΣΥΣΚΕΥΩΝ: ΑΝΑΦΟΡΑ ΠΡΟΕΛΕΥΣΗΣ ΓΙΑ ΑΝΑΓΝΩΡΙΣΜΕΝΑ ΣΥΜΒΟΛΑ ΠΟΥ ΔΙΑΤΗΡΟΥΝΤΑΙ ΣΤΟ ΑΡΧΕΙΟ ΙΑΤΡΙΚΩΝ ΣΥΣΚΕΥΩΝ ΤΟΥ ΚΑΤΑΣΚΕΥΑΣΤΗ; SYMBOLE GRAFICZNE DO OZNACZANIA WYROBU MEDYCZNEGO: REFERENCJE ŹRÓDŁOWE DLA UZNANYCH SYMBOLI ZACHOWANYCH PRZEZ PRODUCENTA W PLIKU WYROBU MEDYCZNEGO; GRAFIKUS SZIMBÓLUMOK ORVOSI ESZKÖZÖK CÍMKÉZÉSÉHEZ: AZ ISMERT SZIMBÓLUMOK REFERENCIAFORRÁSA A GYÁRTÓNÁL LÉVŐ ORVOSI ESZKÖZ FÁJLBAN TALÁLHATÓ; GRAFICKÉ SYMBOLY K OZNAČENÍ ZDRAVOTNICKÉHO PŘÍSTŘEDKU: ODKAZ NA ZDROJ S UZNÁVÁNÝMI SYMBOLY, UCHOVÁVANÝ V VÝROBCE V DOKUMENTACI KE ZDRAVOTNICKÉMU PŘÍSTŘEDKU; TIBBI CIHAZ ETIKETLERI İÇİN GRAFİK SEMBOLLER: TANIMLANMIŞ SEMBOLLER İÇİN KAYNAK REFERANS, TIBBI CIHAZ DOSYASINDA ÜRETİCİDE MEVCUTTUR; GRAFICKÉ SYMBOLY NA OZNAČOVANIE ZDRAVOTNÍCKEJ POMÔCKY: REFERENCIA ZDROJA PRE ROZPOZNANÉ SYMBOLY UCHOVÁVANÉ U VÝROBCU V SÚBORE ZDRAVOTNÍCKEJ POMÔCKY; ГРАФИЧНИ СИМВОЛИ ЗА ЕТИКИРАНЕ НА МЕДИЦИНСКИ УРЕДИ: РЕФЕРЕНТЕН ФАЙЛ НА ИЗТОЧНИКА ЗА ПРИЕТИТЕ СИМВОЛИ, ИЗПОЛЗВАНИ ОТ ПРОИЗВОДИТЕЛЯ ВЪВ ФАЙЛА ЗА МЕДИЦИНСКОТО УСТРОЙСТВО; SIMBOLURI GRAFICE PENTRU ETICHETAREA DISPOZITIVELOR MEDICALE: REFERINȚĂ SURSĂ PENTRU SIMBOLURILE RECUNOSCUTE PĂSTRATE LA PRODUCĂTOR ÎN DOSARUL DISPOZITIVULUI MEDICAL; ГРАФИЧЕСКИЕ СИМВОЛЫ НА ЭТИКЕТКАХ МЕДИЦИНСКИХ ИЗДЕЛИЙ: ИНФОРМАЦИЯ ОБ ОБЩЕПРИНЯТЫХ СИМВОЛАХ СОДЕРЖИТСЯ В СПРАВОЧНИКЕ, ХРАНЯЩЕМСЯ У ПРОИЗВОДИТЕЛЯ В РЕГИСТРАЦИОННОМ ДОСЬЕ МЕДИЦИНСКОГО ИЗДЕЛИЯ; LÄÄKINNÄLLISTEN LAITTEIDEN TUOTETARROISSA ESIINTYVÄT SYMBOLIT: LÄHDEVIITE VALMISTAJAN LÄÄKINNÄLLISTEN LAITTEIDEN TIEDOSTOSSA PIDETYLLE TUNNETUILLE SYMBOLEILLE; GRAFISCHE SYMBOLER FOR MERKING AV MEDISINSK UTSTYR: KILDEHENVISNING FOR ANERKJENTE SYMBOLER SOM OPPBEVARES HOS PRODUSENTEN I FILEN FOR MEDISINSK UTSTYR; MEDITSINIISEADME MÄRGISTUSE GRAAFILISED SÜMBOLID: KASUTATUD SÜMBOLITE VIITEALLIKAS, MIDA TOOTJA HOIAB MEDITSINIISEADME TOIMIKUS; GRAFISKIE SIMBOLI MEDICINSKO IERIČI APŽIMĖJANAI: PIRMAVOTĄ ATSAUCE ATŽIŲJAIEM SIMBOLIEM, KO RAŽOTĄS PATURĖJIS MEDICINISKĄS IERIČIS LIETĄ; MEDICINOS PRIETAISŲ ETIKEČIŲ GRAFINIAI SIMBOLIAI: PIRMINIS SUTARTINIŲ SIMBOLIŲ DOKUMENTAS LAIKOMAS GAMINTOJO PATALPOSE, MEDICINOS PRIETAISO DOKUMENTŲ APLANKE; GRAFIČNI SIMBOLI ZA OZNAČEVANJE MEDICINSKEGA PRIPOMOČKA: REFERENČNI VIR ZA PRIZNANE SIMBOLE, KI JIH V DATOTEKI MEDICINSKEGA PRIPOMOČKA HRANI PROIZVAJALEC; GRAFIČKI SIMBOLI ZA OZNAČAVANJE MEDICINSKOG UREĐAJA: REFERENCA ZA POZNATE SIMBOLE ZADRŽANA KOD PROIZVOĐAČA U DATOTECI MEDICINSKOG UREĐAJA; GRAFIČKI SIMBOLI ZA OZNAČAVANJE MEDICINSKOG SREDSTVA: IZVORNE REFERENCE ZA PRIZNATE SIMBOLE ZADRŽANE SU KOD PROIZVOĐAČA U DATOTECI MEDICINSKOG SREDSTVA; ГРАФИЧКИ СИМВОЛИ ЗА ОЗНАЧУВАЊЕ МЕДИЦИНСКИ УРЕДИ: ИЗВОРНОТО УПАТУВАЊЕ ЗА ОФИЦИЈАЛНИТЕ СИМВОЛИ Е ЗАДРЖАНО КАЈ ПРОИЗВОДИТЕЛОТ ВО ДАТОТЕКАТА ЗА МЕДИЦИНСКИОТ УРЕД; ГРАФИЧНИ СИМВОЛИ НА ЕТИКЕТКАХ МЕДИЦИНСКИХ ВИРОБИВ: ДОВІДКОВА ІНФОРМАЦІЯ ЩОДО СТАНДАРТНИХ СИМВОЛІВ ЗБЕРІГАЄТЬСЯ У ВИРОБНИКА В РЕЄСТРАЦІЙНОМУ ДОСЬЄ МЕДИЦИНСКОГО ВИРОБУ; GRAPHICAL SYMBOLS FOR MEDICAL DEVICE LABELING: REFERENSI SUMBER UNTUK SIMBOL YANG DIAKUI ADALAH DISIMPAN PRODUSEN DALAM FILE PERANGKAT MEDIS; BIỂU TƯỢNG HÌNH ẢNH DÀNH CHO NHÃN DỤNG CỤ Y TẾ: THAM KHẢO NGUỒN ĐỂ BIẾT CÁC BIỂU TƯỢNG CÔNG NHẬN ĐƯỢC GIỮ LẠI TẠI NHÀ SẢN XUẤT TRONG TẬP TIN DỤNG CỤ Y TẾ;

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MITRACLIP™ G4

SYSTEM



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de DEUTSCH	el ΕΛΛΗΝΙΚΑ	ru РУССКИЙ	sr SRPSKI
fr FRANÇAIS	pl POLSKI	fi SUOMI	uk УКРАЇНСЬКА
es ESPAÑOL	hu MAGYAR	no NORSK	mk МАКЕДОНСКИ
it ITALIANO	cs ČESKY	et EESTI KEEL	id INDONESIA
pt PORTUGUÊS	tr TÜRKÇE	lv LATVIEŠU	vi TIẾNG VIỆT
sv SVENSKA	sk SLOVENSKY	lt LIETUVIŲ	ar العربية
nl NEDERLANDS	bg БЪЛГАРСКИ	sl SLOVENŠČINA	

GRAPHICAL SYMBOLS FOR MEDICAL DEVICE LABELING: SOURCE REFERENCE FOR RECOGNIZED SYMBOLS RETAINED AT THE MANUFACTURER IN THE MEDICAL DEVICE FILE; GRAFISCHE SYMBOLE ZUR BESCHRIFTUNG VON MEDIZINPRODUKTEN: QUELLREFERENZDOKUMENT FÜR ANERKANNTE SYMBOLE LIEGT BEIM HERSTELLER IN DER MEDIZINPRODUKTDATATEI VOR; SYMBOLES GRAPHIQUES POUR L'ÉTIQUETAGE DES DISPOSITIFS MÉDICAUX : LES RÉFÉRENCES SOURCES POUR LES SYMBOLES RECONNUS SONT CONSERVÉES CHEZ LE FABRICANT DANS LE DOSSIER DES DISPOSITIFS MÉDICAUX; SÍMBOLOS GRÁFICOS UTILIZADOS EN EL ETIQUETADO DE PRODUCTOS SANITARIOS: LA REFERENCIA ORIGINAL PARA LOS SÍMBOLOS RECONOCIDOS LA GUARDA EL FABRICANTE EN SU ARCHIVO DE PRODUCTOS SANITARIOS; SIMBOLI GRAFICI PER L'ETICHETTATURA DI DISPOSITIVI MEDICALI: FARE RIFERIMENTO AL TESTO SORGENTE PER I SIMBOLI RICONOSCIUTI CONSERVATI PRESSO IL PRODUTTORE NEL FILE DISPOSITIVI MEDICALI; SÍMBOLOS GRÁFICOS PARA ROTULAGEM DE DISPOSITIVOS MÉDICOS: REFERÊNCIA DE FONTE PARA SÍMBOLOS RECONHECIDOS RETIDOS PELO FABRICANTE NO FICHEIRO DO DISPOSITIVO MÉDICO; GRAFISKA SYMBOLER FÖR MÄRKNING AV MEDICINSK UTRUSTNING: KÄLLREFERENS FÖR ERKÄNDA SYMBOLER SOM FINNS KVAR HOS TILLVERKAREN I FILEN FÖR MEDICINSK UTRUSTNING; GRAFISCHE SYMBOLEN VOOR DE ETIKETTERING VAN MEDISCHE HULPMIDDELEN: BRONVERMELDING VOOR ERKENDE SYMBOLEN WORDT DOOR DE FABRIKANT BEWAARD IN HET DOSSIER VAN HET MEDISCH HULPMIDDEL; GRAFISCHE SYMBOLER FOR MÆRKNING AF MEDICINSK PRODUKT: KILDEHENVISNINGER TIL ANERKENDTE SYMBOLER OPBEVARES HOS PRODUCENTEN I FILEN VEDRØRENDE DET MEDICINSKE PRODUKT; ΓΡΑΦΙΚΑ ΣΥΜΒΟΛΑ ΓΙΑ ΤΗ ΣΗΜΑΝΣΗ ΙΑΤΡΙΚΩΝ ΣΥΣΚΕΥΩΝ: ΑΝΑΦΟΡΑ ΠΡΟΕΛΕΥΣΗΣ ΓΙΑ ΑΝΑΓΝΩΡΙΣΜΕΝΑ ΣΥΜΒΟΛΑ ΠΟΥ ΔΙΑΤΗΡΟΥΝΤΑΙ ΣΤΟ ΑΡΧΕΙΟ ΙΑΤΡΙΚΩΝ ΣΥΣΚΕΥΩΝ ΤΟΥ ΚΑΤΑΣΚΕΥΑΣΤΗ; SYMBOL E GRAFICZNE DO OZNACZANIA WYROBU MEDYCZNEGO: REFERENCJE ŹRÓDŁOWE DLA UZNANYCH SYMBOLI ZACHOWANYCH PRZEZ PRODUCENTA W PLIKU WYROBU MEDYCZNEGO; GRAFIKUS SZIMBÓLUMOK ORVOSI ESZKÖZÖK CÍMKÉZÉSÉHEZ: AZ ISMERT SZIMBÓLUMOK REFERENCIAFORRÁSA A GYÁRTÓNÁL LÉVŐ ORVOSI ESZKÖZ FÁJLBAN TALÁLHATÓ; GRAFICKÉ SYMBOLY K OZNAČENÍ ZDRAVOTNICKÉHO PROSTŘEDKU: ODKAZ NA ZDROJ S UZNÁVÁNÝMI SYMBOLY, UCHOVÁVANÝ U VÝROBCE V DOKUMENTACI KE ZDRAVOTNICKÉMU PROSTŘEDKU; TIBBİ CİHAZ ETİKETLERİ İÇİN GRAFİK SEMBOLLER: TANIMLANMIŞ SEMBOLLER İÇİN KAYNAK REFERANS, TIBBİ CİHAZ DOSYASINDA ÜRETİCİDE MEVCUTTUR; GRAFICKÉ SYMBOLY NA OZNAČOVANIE ZDRAVOTNÍCKEJ POMÔCKY: REFERENCIA ZDROJA PRE ROZPOZNANÉ SYMBOLY UCHOVÁVANÉ U VÝROBCU V SÚBORE ZDRAVOTNÍCKEJ POMÔCKY; ГРАФИЧНИ СИМВОЛИ ЗА ЕТИКИРАНЕ НА МЕДИЦИНСКИ УРЕДИ: РЕФЕРЕНТЕН ФАЙЛ НА ИЗТОЧНИКА ЗА ПРИЕТИТЕ СИМВОЛИ, ИЗПОЛЗВАНИ ОТ ПРОИЗВОДИТЕЛЯ ВЪВ ФАЙЛА ЗА МЕДИЦИНСКОТО УСТРОЙСТВО; SIMBOLURI GRAFICE PENTRU ETICHETAREA DISPOZITIVELOR MEDICALE: REFERINȚĂ SURSĂ PENTRU SIMBOLURILE RECUNOSCUTE PĂSTRATE LA PRODUCĂTOR ÎN DOSARUL DISPOZITIVULUI MEDICAL; ГРАФИЧЕСКИЕ СИМВОЛЫ НА ЭТИКЕТКАХ МЕДИЦИНСКИХ ИЗДЕЛИЙ. ИНФОРМАЦИЯ ОБ ОБЩЕПРИНЯТЫХ СИМВОЛАХ СОДЕРЖИТСЯ В СПРАВОЧНИКЕ, ХРАНЯЩЕМСЯ У ПРОИЗВОДИТЕЛЯ В РЕГИСТРАЦИОННОМ ДОСЬЕ МЕДИЦИНСКОГО ИЗДЕЛИЯ; LÄÄKINNÄLLISTEN LAITTEIDEN TUOTETARROISSA ESIINTYVÄT SYMBOLIT: LÄHDEVIITE VALMISTAJAN LÄÄKINNÄLLISTEN LAITTEIDEN TIEDOSTOSSA PIDETYLLE TUNNETUILLE SYMBOLEILLE; GRAFISCHE SYMBOLER FOR MÆRKNING AV MEDISINSK UTSTYR: KILDEHENVISNING FOR ANERKJENTE SYMBOLER SOM OPPBEVARES HOS PRODUSENTEN I FILEN FOR MEDISINSK UTSTYR; MEDITSIIINISEADME MÄRGISTUSE GRAAFILISED SÜMBOLID: KASUTATUD SÜMBOLITE VIITEALLIKAS, MIDA TOOTJA HOIAB MEDITSIIINISEADME TOIMIKUS; GRAFISKIE SIMBOLI MEDICINSKO IERIČU APŽIMĖSANAI: PIRMAVOTA ATSAUCE ATŽITAJIEM SIMBOLIEM, KO RAŽOTĄS PATURĖJIS MEDICINSKĄS IERIES LIETĄ; MEDICINOS PRIETAISŲ ETIKEČIŲ GRAFINIAI SIMBOLIAI: PIRMINIS SUTARTINIŲ SIMBOLIŲ DOKUMENTAS LAIKOMAS GAMINTOJO PATALPOSE, MEDICINOS PRIETAISO DOKUMENTŲ APLANKĖ; GRAFIČNI SIMBOLI ZA OZNAČEVANJE MEDICINSKEGA PRIPOMOČKA: REFERENČNI VIR ZA PRIZNANE SIMBOLE, KI JIH V DATOTEKI MEDICINSKEGA PRIPOMOČKA HRANI PROIZVAJALEC; GRAFIČKI SIMBOLI ZA OZNAČAVANJE MEDICINSKOG UREDAJA: REFERENCA ZA POZNATE SIMBOLE ZADRŽANA KOD PROIZVOĐAČA U DATOTEKI MEDICINSKOG UREDAJA; GRAFIČKI SIMBOLI ZA OZNAČAVANJE MEDICINSKOG SREDSTVA: IZVORNE REFERENCE ZA PRIZNATE SIMBOLE ZADRŽANE SU KOD PROIZVOĐAČA U DATOTEKI MEDICINSKOG SREDSTVA; ГРАФИЧНИ СИМВОЛИ НА ЕТИКЕТКАХ МЕДИЧНИХ ВИРОБІВ: ДОВІДКОВА ІНФОРМАЦІЯ ЩОДО СТАНДАРТНИХ СИМВОЛІВ ЗБЕРІГАЄТЬСЯ У ВИРОБНИКА В РЕЄСТРАЦІЙНОМУ ДОСЬЕ МЕДИЧНОГО ВИРОБУ; ГРАФИЧКИ СИМВОЛИ ЗА ОЗНАЧУВАНЬ МЕДИЦИНСКИ УРЕДИ: ІЗВОРНОТО УПАТУВАНЬ ЗА ОФІЦІАЛНІТЕ СИМВОЛИ Є ЗАДРЖАНО КАЖ ПРОИЗВОДИТЕЛІ ВО ДАТОТЕКАТА ЗА МЕДИЦИНСКИОТ УРЕД; GRAPHICAL SYMBOLS FOR MEDICAL DEVICE LABELING: REFERENSI SUMBER UNTUK SIMBOL YANG DIAKUI ADALAH DISIMPAN PRODUSEN DALAM FILE PERANGKAT MEDIS; BIỂU TƯỢNG HÌNH ẢNH DÀNH CHO NHÃN DỤNG CỤ Y TẾ: THAM KHẢO NGUỒN ĐỂ BIẾT CÁC BIỂU TƯỢNG CÔNG NHẬN ĐƯỢC GIỮ LẠI TẠI NHÀ SẢN XUẤT TRONG TẬP TIN DỤNG CỤ Y TẾ; رموز رسومية لتصنيف الأجهزة الطبية: مرجع للرموز المعتمدة تحتفظ به شركة التصنيع في ملف الجهاز الطبي

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Do not use if package is damaged; Das Produkt nicht verwenden, wenn die Packung beschädigt ist; Ne pas utiliser ce produit si l'emballage est endommagé; No utilizar el producto si el envase está dañado; Non utilizzare se la confezione è danneggiata; Não utilizar se a embalagem estiver danificada; Använd inte produkten om förpackningen är skadad; Gebruik het product niet als de verpakking beschadigd is; Må ikke anvendes, hvis pakningen er beskadiget; Μη χρησιμοποιείτε το προϊόν, εάν η συσκευασία είναι κατεστραμμένη; Nie używać, jeśli opakowanie zostało uszkodzone; Ne használja, ha a csomagolás sérült; Nepoužívejte, je-li obal poškozen; Ambalaj hasar görmüşse kullanmayın; Nepoužívajte, ak je obal poškodený; Не используйте, ако пакетът е повреден; Nu utilizați dacă ambalajul este deteriorat; Не использовать, если упаковка повреждена; Ei saa käyttää, jos pakkaus on vaurioitunut; Må ikke brukes hvis emballasjen er skadet; Mitte kasutada, kui pakend on kahjustatud; Nelietot, ja iepakojums ir bojāts; Nenaudokite, jeigu pakuotė pažeista; Ne uporabljajte, če je embalaža poškodovana; Nemojte upotrebljavati ako je pakiranje oštećeno; Ne koristiti ako je pakovanje oštećeno; Не використовувати, якщо пакування пошкоджене; Не употребляйте го ако е оштетена амбалажа; Jangan digunakan jika kemasan rusak; Không được sử dụng nếu bao bì bị hỏng; تجنب الاستخدام إذا كانت العبوة تالفة



Packaging unit; Packungseinheit; Unité de conditionnement; Unidad de envasado; Unità di imballaggio; Unidade de embalagem; Förpackningsenhet; Verpakkingseenheid; Pakkeenhet; Μονάδα συσκευασίας; Jednostka opakowania; Az eszköz csomagolása; Jednotka balení; Ambalaj Birimi; Jednotka balenia; Опаковъчна единица; Unitate de ambalare; Упаковочная единица; Pakkausyksikkö; Pakningsenhet; Pakkeühik; Iepakojuma vienība; Pakuotė; Embalažna enota; Ambalažna jedinica; Jedinica pakovanja; Индивидуална упаковка; Единица амбалажа; Unit Kemasan; Đơn vị Đóng gói; وحدة العبوة



Caution; Vorsicht; Attention; Precaución; Attenzione; Atenção; Obs; Voorzichtigheid; Forsigtig; Προσοχή; Uwaga; Figyelem; Urozornění; Dikkat; Urozornenie; Внимание; Atentie; Предостережение; Huomio; Forsiktig; Ettevaatust!; Uzmanību!; Dămesio; Pozor!; Opze; Uvaga; Внимание; Perhatian; Cần trọng; تنبيه



MR conditional; Bedingt MRT-kompatibel; Compatible avec l'IRM sous conditions; Compatibilidad condicionada con la RM; A compatibilità con RM condizionata; Condicionado ao ambiente de ressonância magnética; MR-säker under specifika betingelser; Onder bepaalde voorwaarden MR-veilig; MR-betinget; Συμβατό με μαγνητική τομογραφία; Warunkowo bezpieczne w rezonansie magnetycznym (MR); MR-környezetben feltételeken biztonságos; Bezpečné při vyšetření MR za určitých podmínek; MR Koşullu; Podmienneče kompatibilné s prostredím MR; Безопасен при определени условия на ЯМР; Acceptabil pentru RMN; Не является противопоказанием к проведению МРТ; MRI-ehdollinen; MR-tilpasse; MRT-keskkonnas turvaline kindlate kasutustingimuste järgimisel; Saderīgs ar MR; MRT (sąlyginis); Varna uporaba v okolju z MR pod določenimi pogoji; Sigurna uporaba v okolini s MR-om pod određenim uvjetima; Uslovno bezbedno korišćenje u MR okruženju; Не є протипоказанням для проведення МРТ; Условено компатибелен за МР; MR Conditional; Điều kiện MR; شروط للدخول للرنين المغناطيسي



Date of manufacture; Herstellungsdatum; Date de fabrication; Fecha de fabricación; Data di produzione; Data de fabrico; Tillverkningsdatum; Productiedatum; Fremstillingsdato; Ημερομηνία κατασκευής; Data produkcyj; A gyártás dátuma; Datum výroby; Üretim Tarihi; Dátum výroby; Дата на производство; Data fabricației; Дата изготовления; Valmistuspäivämäärä; Tilvirkningsdato; Tootmiskuuapäev; Ražošanas datums; Pagaminimo data; Datum izdelave; Datum proizvodnje; Datum proizvodnje; Дата виробництва; Датум на производство; Tanggal pembuatan; Ngày sản xuất; تاريخ التصنيع



Unique device identifier; Eindeutige Produktkennung; Identifiant unique du dispositif; Identificador de dispositivo único; Identificativo univoco del dispositivo; Identificador exclusivo do dispositivo; Unik enhetsidentifikator; Unieke hulpmiddelcode; Unik udstyrsidentifikator; Μοναδικό αναγνωριστικό συσκευής; Unikálny identifikátor urzdzenia; Egyeséges termékaazonosító kód; Jedinečný identifikátor zařízení; Benzersiz cihaz tanımlayıcısı; Jedinečný identifikátor pomôcky; Унікален ідентифікатор на изделиї; Numărul unic de identificare a dispozitivului; Уникальный идентификатор устройства; Yksilöllinen laitetunniste; Unik enhetsidentifikasjon; Seadme kordumatu tuvastamine; Unikāls ierices identifikators; Unikalus prietaiso identifikatorius; Edinstveni identifikator pripomočka; Jedinstvena oznaka uređaja; Jedinstveni identifikator medicinskog sredstva; Унікальний ідентифікатор пристрою; Идентификација специфична за уредот; Identifikasi perangkat unik; Mã nhận dạng thiết bị duy nhất; معرف الجهاز الفريد



Authorized representative in the European Community; Bevollmächtigte Vertretung in der Europäischen Gemeinschaft; Représentant agréé pour la Communauté européenne; Representante autorizado en la Comunidad Europea; Rappresentante autorizzato nella Comunità europea; Representante autorizado na Comunidade Europeia; Auktoriserad representant i Europeiska gemenskapen; In de Europese Gemeenschap gevestigde gemachtigde; Autoriseret repræsentant i Det Europæiske Fællesskab; Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα; Autoryzowany przedstawiciel we Wspólnocie Europejskiej; Hivatalos képviselő az Európai Közösségekben; Oprávněný zástupce v Evropském společenství; Avrupa Topluluğu Yetkili Temsilcisi; Oprávněný zástupce v Evropském společenství; Упълномощен представител в Европейската общност; Reprezentant autorizat în Comunitatea Europeană; Уполномоченный представитель в ЕС; Valtuutettu edustaja Euroopan yhteisössä; Autorisert representant i Det europeiske fellesskap; Volitatud esindaja Euroopa Ühenduses; Pilnvarost pārstāvis Eiropas Savienībā; Įgaliotasis atstovas Europos Bendrijoje; Pooblašćeni predstavnik v Evropski skupnosti; Ovlašteni predstavnik u Europskoj zajednici; Ovlašćeni predstavnik u Evropskoj zajednici; Уповноважений представник у ЕС; Овластен претставник во Европската заедница; Perwakilan resmi di komunitas Eropa; Đại diện được ủy quyền tại Cộng đồng châu Âu; ممثل معتمد في المجموعة الأوروبية

GRAPHICAL SYMBOLS FOR MEDICAL DEVICE LABELING; SOURCE REFERENCE FOR RECOGNIZED SYMBOLS RETAINED AT THE MANUFACTURER IN THE MEDICAL DEVICE FILE; GRAFISCHE SYMBOLE ZUR BESCHRIFTUNG VON MEDIZINPRODUKTEN; QUELLREFERENZDOKUMENT FÜR ANERKANNTE SYMBOLE LIEGT BEIM HERSTELLER IN DER MEDIZINPRODUKTDATEI VOR; SYMBOLES GRAPHIQUES POUR L'ÉTIQUETAGE DES DISPOSITIFS MÉDICAUX : LES RÉFÉRENCES SOURCES POUR LES SYMBOLES RECONNUS SONT CONSERVÉES CHEZ LE FABRICANT DANS LE DOSSIER DES DISPOSITIFS MÉDICAUX; SÍMBOLOS GRÁFICOS UTILIZADOS EN EL ETIQUETADO DE PRODUCTOS SANITARIOS: LA REFERENCIA ORIGINAL PARA LOS SÍMBOLOS RECONOCIDOS LA GUARDA EL FABRICANTE EN SU ARCHIVO DE PRODUCTOS SANITARIOS; SIMBOLI GRAFICI PER L'ETICHETTATURA DI DISPOSITIVI MEDICALI: FARE RIFERIMENTO AL TESTO SORGENTE PER I SIMBOLI RICONOSCIUTI CONSERVATI PRESSO IL PRODUTTORE NEL FILE DISPOSITIVI MEDICALI; SÍMBOLOS GRÁFICOS PARA ROTULAGEM DE DISPOSITIVOS MÉDICOS: REFERÊNCIA DE FONTE PARA SÍMBOLOS RECONHECIDOS RETIDOS PELO FABRICANTE NO FICHEIRO DO DISPOSITIVO MÉDICO; GRAFISKA SYMBOLER FÖR MÄRKNING AV MEDICINSK UTRUSTNING: KÄLLREFERENS FÖR ERKÄNDA SYMBOLER SOM FINNS KVAR HOS TILLVERKAREN I FILEN FÖR MEDICINSK UTRUSTNING; GRAFISCHE SYMBOLEN VOOR DE ETIKETTERING VAN MEDISCHE HULPMIDDELEN: BRONVERMELDING VOOR ERKENDE SYMBOLEN WORDT DOOR DE FABRIKANT BEWAARD IN HET DOSSIER VAN HET MEDISCH HULPMIDDEL; GRAFISCHE SYMBOLER FOR MÆRKNING AF MEDICINSK PRODUKT: KILDEHENVISNINGER TIL ANERKENDTE SYMBOLER OPBEVARES HOS PRODUCENTEN I FILEN VEDRØRENDE DET MEDICINSKE PRODUKT; ΓΡΑΦΙΚΑ ΣΥΜΒΟΛΑ ΓΙΑ ΤΗ ΣΗΜΑΝΣΗ ΙΑΤΡΙΚΩΝ ΣΥΣΚΕΥΩΝ: ΑΝΑΦΟΡΑ ΠΡΟΣΕΛΕΥΣΗΣ ΓΙΑ ΑΝΑΓΝΩΡΙΖΜΕΝΑ ΣΥΜΒΟΛΑ ΠΟΥ ΔΙΑΤΗΡΟΥΝΤΑΙ ΣΤΟ ΑΡΧΕΙΟ ΙΑΤΡΙΚΩΝ ΣΥΣΚΕΥΩΝ ΤΟΥ ΚΑΤΑΣΚΕΥΑΣΤΗ; SYMBOL E GRAFICZNE DO OZNACZANIA WYROBU MEDYCZNEGO: REFERENCJE ŹRÓDŁOWE DLA UZNANYCH SYMBOLI ZACHOWANYCH PRZECZ PRODUCENTA W PLIKU WYROBU MEDYCZNEGO; GRAFIKUS SZIMBÓLUMOK ORVOSI ESZKÖZÖK CÍMKÉZÉSÉHEZ: AZ ISMERT SZIMBÓLUMOK REFERENCIAFORRÁSA A GYÁRTÓNÁL LÉVŐ ORVOSI ESZKÖZ FÁJLBAN TALÁLHATÓ; GRAFICKÉ SYMBOLY K OZNAČENÍ ZDRAVOTNICKÉHO PROSTŘEDKU: ODKAZ NA ZDROJ S UZNÁVANÝMI SYMBOLY, UCHOVÁVANÝ U VÝROBCE V DOKUMENTACI KE ZDRAVOTNICKÉMU PROSTŘEDKU; TIBBİ CİHAZ ETİKETLERİ İÇİN GRAFİK SEMBOLLER: TANIMLANMIŞ SEMBOLLER İÇİN KAYNAK REFERANS, TIBBİ CİHAZ DOSYASINDA ÜRETİCİDE MEVCUTTUR; GRAFICKÉ SYMBOLY NA OZNAČOVANIE ZDRAVOTNÍCKEJ POMÔCKY: REFERENCIA ZDROJA PRE ROZPOZNANÉ SYMBOLY UCHOVÁVANÉ U VÝROBCU V SÚBORE ZDRAVOTNÍCKEJ POMÔCKY; ГРАФИЧНИ СИМВОЛИ ЗА ЕТИКИРАНЕ НА МЕДИЦИНСКИ УРЕДИ: РЕФЕРЕНТЕН ФАЙЛ НА ИЗТОЧНИКА ЗА ПРИЕТИТЕ СИМВОЛИ, ИЗПОЛЗВАНИ ОТ ПРОИЗВОДИТЕЛЯ ВЪВ ФАЙЛА ЗА МЕДИЦИНСКОТО УСТРОЙСТВО; SIMBOLURI GRAFICE PENTRU ETICHETAREA DISPOZITIVELOR MEDICALE: REFERINȚĂ SURSĂ PENTRU SIMBOLURILE RECUNOSCUTE PĂSTRATE LA PRODUCĂTOR ÎN DOSARUL DISPOZITIVULUI MEDICAL; ГРАФИЧЕСКИЕ СИМВОЛЫ НА ЭТИКЕТКАХ МЕДИЦИНСКИХ ИЗДЕЛИЙ. ИНФОРМАЦИЯ ОБ ОБЩЕПРИНЯТЫХ СИМВОЛАХ СОДЕРЖИТСЯ В СПРАВОЧНИКЕ, ХРАНЯЩЕМСЯ У ПРОИЗВОДИТЕЛЯ В РЕГИСТРАЦИОННОМ ДОСЬЕ МЕДИЦИНСКОГО ИЗДЕЛИЯ; LÄÄKINNÄLISTEN LAITTEIDEN TUOTETARROISSA ESINTYVÄT SYMBOLIT: LÄHDEVIITE VALMISTAJAN LÄÄKINNÄLISTEN LAITTEIDEN TIEDOSTOSSA PIDETYLLE TUNNETUILLE SYMBOLEILLE; GRAFISCHE SYMBOLER FOR MERKING AV MEDISINSK UTSTYR: KILDEHENVISNING FOR ANERKJENTE SYMBOLER SOM OPBEVARES HOS PRODUSENTEN I FILEN FOR MEDISINSK UTSTYR; MEDITSINIISEADME MÄRGISTUSE GRAAFILISED SÜMBOLID: KASUTATUD SÜMBOLITE VIITEALLIKAS, MIDA TOOTJA HOIAB MEDITSINIISEADME TOIMIKUS; GRAFISCHE SIMBOLI MEDICINISKO IERIČU APŽIŲĖSANAI: PIRMAVOTA ATSAUCE ATŽIŲIAJAM SIMBOLIEM, KO RAŽOTĖJAS PATURĖJIS MEDICINISKĖS IERČES LIETĖ; MEDICINOS PRIETAISŲ ETIKEČIŲ GRAFINIAI SIMBOLIAI: PIRMINIS SUTARTINIŲ SIMBOLIŲ DOKUMENTAS LAIKOMAS GAMINTOJO PATALPOSE, MEDICINOS PRIETAISŲ DOKUMENTŲ APLANKE; GRAFIČNÍ SIMBOLY ZA OZNAČOVANJE MEDICINSKEGA PRIPOMOČKA: REFERENČNI VIR ZA PRIZNANE SIMBOLE, KI JIH V DATOTEKI MEDICINSKEGA PRIPOMOČKA HRANI PROIZVAJALEC; GRAFIČKI SIMBOLI ZA OZNAČAVANJE MEDICINSKOG UREĐAJA: REFERENCA ZA POZNATE SIMBOLE ZADRŽANA KOD PROIZVOĐAČA U DATOTEKI MEDICINSKOG UREĐAJA; GRAFIČKI SIMBOLI ZA OZNAČAVANJE MEDICINSKOG SREDSTVA: IZVORNE REFERENCE ZA PRIZNATE SIMBOLE ZADRŽANE SU KOD PROIZVOĐAČA U DATOTEKI MEDICINSKOG SREDSTVA; ГРАФИЧНИ СИМВОЛИ НА ЕТИКЕТКАХ МЕДИЧНИХ ВИРОБІВ: ДОВІДКОВА ІНФОРМАЦІЯ ЩОДО СТАНДАРТНИХ СИМВОЛІВ ЗБЕРІГАЄТЬСЯ У ВИРОБНИКА В РЕЄСТРАЦІЙНОМУ ДОСЬЄ МЕДИЧНОГО ВИРОБУ; ГРАФИЧКИ СИМБОЛИ ЗА ОЗНАЧУВАНЬЕ МЕДИЦИНСКИ УРЕДИ: ИЗВОРОТО УПАТУВАНЬЕ ЗА ОФИЦІАЛНІТЕ СИМБОЛИ Е ЗАДРЖАНО КАК ПРОИЗВОДИТЕЛОТ ВО ДАТОТЕКАТА ЗА МЕДИЦИНСКИОТ УРЕД; GRAPHICAL SYMBOLS FOR MEDICAL DEVICE LABELING: REFERENCE SUMBER UNTUK SIMBOL YANG ADALAH DISIMPAN PRODUSEN DALAM FILE PERANGKAT MEDIS; BIỂU TƯỢNG HÌNH ẢNH DÀNH CHO NHÂN DỤNG CỤ Y TẾ: THAM KHẢO NGUỒN ĐỂ BIẾT CÁC BIỂU TƯỢNG CÔNG NHẬN ĐƯỢC GIỮ LẠI TẠI NHÀ SẢN XUẤT TRONG TẬP TIN DỤNG CỤ Y TẾ; رموز رسومية لتصنيف الأجهزة الطبية: مرجع للرموز المعتمدة تحتفظ به شركة التصنيع في ملف الجهاز الطبي

R ONLY

CAUTION: Federal law restricts this device to sale by or on the order of a physician; VORSICHT: Laut US-Bundesgesetz darf dieses Produkt nur an Ärzte oder auf deren Anordnung verkauft werden; ATTENTION : La loi fédérale limite la vente de ce dispositif par un médecin ou sur ordonnance médicale; PRECAUCIÓN: La legislación federal restringe la venta de este dispositivo a médicos o bajo la prescripción de un médico; ATTENZIONE: la legge federale limita la vendita di questo dispositivo ai medici o su prescrizione medica; ATENÇÃO: A legislação federal apenas permite a venda deste dispositivo a médicos ou mediante prescrição médica; OBS! Enligt amerikansk federal lag får detta instrument endast säljas av eller på ordination av läkare; LET OP: Krachtens de federale wetgeving mag dit instrument uitsluitend door of op voorschrift van een arts worden verkocht; FORSIGTIG: Amerikansk lovgivning begrænser dette udstyr til salg af en læge eller efter dennes ordination; ΠΡΟΣΟΧΗ: Η ομοσπονδιακή νομοθεσία των ΗΠΑ επιτρέπει την πώληση αυτής της συσκευής μόνο από ιατρό ή κατόπιν εντολής ιατρού; UWAGA: przepisy federalne dopuszczają sprzedaż tego urządzenia wyłącznie przez lub z przepisu lekarza; FIGYELEM: A szövetségi (USA) törvények értelmében ezt az eszközt csak orvos által, vagy orvosi rendelvényre szabad eladni; UPOZORNĚNÍ: Podle federálních zákonů USA je prodej tohoto zařízení omezen pouze na lékaře nebo lékařský předpis; DIKKAT: Federal yasalara göre bu cihaz yalnızca bir hekim tarafından ya da bir hekimin siparişiyle satılabilir; UPOZORNENIE: Federálny zákon (USA) obmedzuje predaj tejto pomôcky na lekára alebo lekársky predpis; ВНИМАНИЕ: Федералното законодателство на САЩ налага ограничението това устройство да се продава само на лекари или по поръчка на лекари; ATENȚIE: Legea federală restricționează comercializarea acestui aparat doar de către sau pe baza comenzii unui medic; ВНИМАНИЕ! Федеральное законодательство разрешает продажу данного устройства только врачам или по их заказу; HUOMIO: Yhdysvaltain liittovaltion lain mukaan tämän laitteen saa myydä vain lääkäri tai lääkärin määräyksestä; FORSIKTIG: Ifølge amerikansk lovgivning kan dette utstyret bare selges av eller etter rekvisisjon fra lege; ETTEVAATUST! Föderaalseadused lubavad seda seadet müüa ainult arstidel või arsti korraldusel; UZMANĪBU! ASV federālie tiesību akti šo ierīci ļauj iegādāties tikai ārstam vai pēc ārsta pasūtījuma; DÉMESIO: pagal federalinius įstatymus šį prietaisą galima parduoti tik gydytojui arba gydytojo nurodymu; POZOR: Po zvezni zakonodaji ZDA je prodaja ali naročanje tega pripomočka dovoljeno samo zdravnikom; OPREZ: Saveznim je zakonom (SAD-a) prodaja ovog uređaja ograničena na liječnike ili prema njihovoj nagolu; OPREZ: Savezni zakoni ograničavaju prodaju ovog uređaja na prodaju od strane lekara ili po njegovom nagolu; УВАГА! Відповідно до федерального законодавства США, продаж цього пристрою дозволено лише лікарям або за їхнім призначенням; ВНИМАНИЕ: Федералниот закон ограничува продажбата на овој уред да може да се врши само од страна или по налог од лекар; PERHATIAN: Undang-undang Federal (AS) membatasi penjualan perangkat ini hanya oleh atau atas perintah dokter; CẢN TRONG: Luật liên bang hạn chế chỉ mua dụng cụ này từ hoặc theo yêu cầu của bác sĩ; تبيہ: يحظر القانون الفيدرالي بيع هذا الجهاز إلا بواسطة طبيب أو بأمر منه.

INSTRUCTIONS FOR USE

MITRACLIP™ G4 SYSTEM

MitraClip™ G4 Clip Delivery System CDS07

MitraClip™ G4 Steerable Guide Catheter SGC0702

REUSABLE ACCESSORIES

Stabilizer SZR01ST

Lift LFT01ST

Support Plate PLT01ST

WARNING: Read all instructions carefully. Failure to follow these instructions, warnings and precautions may lead to device damage or patient injury. Use of the MitraClip™ G4 System should be restricted to those physicians trained to perform invasive endovascular and transseptal procedures and to those physicians trained in the proper use of the system.

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1.0 INTENDED USE

The MitraClip™ G4 System is intended for reconstruction of the insufficient mitral valve through tissue approximation.

2.0 TARGET PATIENT POPULATION

Patients with significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus (degenerative MR) who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.

Patients with symptomatic, moderate-to-severe or severe secondary (or functional) mitral regurgitation (MR ≥ Grade 3+) with a left ventricular ejection fraction (LVEF) ≥ 20% and ≤ 50%, and a left ventricular end systolic dimension (LVESD) ≤ 70 mm whose symptoms and MR severity persist despite maximally tolerated GDMT as determined by a team of physicians (heart team) experienced in the evaluation and treatment of heart failure and mitral valve disease.

Benefit over medical therapies has not been clearly demonstrated for other patient populations. The prescribing clinician should carefully weigh the potential risks and benefits of this intervention in light of the specific clinical characteristics in an individual patient.

3.0 CONTRAINDICATIONS

Patients with the following conditions should not be treated with the MitraClip™ G4 System:

- Patients who cannot tolerate, including allergy or hypersensitivity to, procedural anticoagulation or post procedural anti-platelet regimen
- Patients with known hypersensitivity to clip components (nickel / titanium, cobalt, chromium, polyester), or with contrast sensitivity
- Active endocarditis of the mitral valve
- Rheumatic mitral valve disease
- Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus

4.0 CLIP SIZE CONSIDERATIONS

- When selecting a Clip length, consider the leaflet length needed to engage all the frictional elements for leaflet insertion.
 - MitraClip™ G4 NT and MitraClip™ G4 NTW Clip arm length is maximum 9 mm with 6 mm of leaflet insertion needed for complete frictional element engagement.
 - MitraClip™ G4 XT and MitraClip™ G4 XTW Clip arm length is maximum 12 mm with 9 mm of leaflet insertion needed for complete frictional element engagement.
 - Note: Mitral Valve Area and gradient concerns also need to be considered when selecting a longer Clip size.
- When selecting a Clip width, consider selecting a wider Clip for broader jets and greater MR severity.

Note: Mitral Valve Area and gradient concerns also need to be considered when selecting a wider Clip size.

5.0 WARNINGS

The following anatomic considerations may result in suboptimal leaflet insertion and / or MitraClip™ G4 implantation. Patients with these conditions who undergo the MitraClip™ G4 procedure may have an increased risk of serious adverse events which may be minimized with proper device usage and echocardiographic assessment. These events include the potential for increased procedure time, tissue injury, and / or worsening MR which may require additional MitraClip™ G4 intervention or surgical treatment.

- Severe leaflet calcification in the grasping area
- Severe calcification of the annulus and / or subvalvular apparatus, such as the chordae tendinae
- Severely restricted posterior leaflet
- Cleft or perforation in the grasping area
- Leaflet Flail gap ≥ 10 mm and / or Leaflet Flail width ≥ 15 mm
- Coaptation length < 2 mm
- Intracardiac mass

The following anatomic considerations may result in serious adverse events, including tissue injury, worsening MR or in the case of the mitral valve area, mitral stenosis. If these events were to occur, they can require additional percutaneous or surgical intervention for treatment. The occurrence of these events can be minimized with appropriate preoperative evaluation of the valve anatomy and regurgitant jet.

- Mitral valve orifice area < 4 cm²
- Primary regurgitant jet outside of the A2-P2 area and / or presence of a clinically significant 2nd jet

Patients with the following considerations in whom the Steerable Guide Catheter (SGC) is used may have an increased risk of having a serious adverse event. This may be avoided with preoperative evaluation and proper device usage.

- Previous interatrial septal patch or prosthetic atrial septal defect (ASD) closure device which could result in significant difficulty in visualization or technical challenges during transseptal puncture and / or introducing the SGC into the left atrium.
- Known or suspected unstable angina or myocardial infarction within the last 12 weeks could increase the procedural morbidity and mortality, due to increased hemodynamic stress secondary to general anesthesia.
- Patients with active infection have an increased risk of developing an intraoperative and / or postoperative infection, such as sepsis or soft tissue abscess.
- Known or suspected left atrial myxoma could result in thromboembolism and tissue injury due to difficulty with device positioning.
- Recent cerebrovascular event (CVA) may increase the procedural morbidity associated with a transcatheter intervention, such as recurrent stroke.

Use caution when treating patients with hemodynamic instability requiring inotropic support or mechanical heart assistance due to the increased risk of mortality in this patient population. The safety and effectiveness of MitraClip in these patients has not been evaluated.

Patients with a rotated heart due to prior cardiac surgery in whom the System is used may have a potential risk of experiencing adverse events such as atrial perforation, cardiac tamponade, tissue damage, and embolism which may be avoided with preoperative evaluation and proper device usage.

The MitraClip™ G4 Implant should be implanted with sterile techniques using fluoroscopy and echocardiography (e.g. transesophageal [TEE] and transthoracic [TTE]) in a facility with on-site cardiac surgery and immediate access to a cardiac operating room.

Read all instructions carefully. Use universal precautions for biohazards and sharps while handling the MitraClip™ G4 System to avoid user injury. Failure to follow these instructions, warnings and precautions may lead to device damage, user injury, or patient injury including:

- MitraClip™ G4 Implant erosion, migration or malposition
- Failure to deliver MitraClip™ G4 Implant to the intended site
- Difficulty or failure to retrieve MitraClip™ G4 system components

For the Clip Delivery System and Steerable Guide Catheter only: this device is designed for single use only. Cleaning, re-sterilization and / or re-use may result in infections, malfunction of the device and other serious injury or death.

For the Steerable Guide Catheter and Delivery Catheter only:

- The Guide Catheter: the distal 65 cm of the Steerable Guide Catheter with the exception of the distal soft tip, is coated with a hydrophilic coating.
- The Delivery Catheter: coated with a hydrophilic coating for a length of approximately 131 cm.
- Failure to prepare the device as stated in these instructions and failure to handle the device with care could lead to additional intervention or serious adverse event.

NOTE the "Use by" date specified on the package. Inspect all product prior to use. Do not use if the package is open or damaged, or if product is damaged.

The MitraClip™ G4 System has not been tested in pregnant women. Effects on the developing fetus have not been studied. The risks and reproductive effects are unknown at this time.

Safety and effectiveness of the MitraClip™ G4 System has not been established in pediatric patients.

6.0 PRECAUTIONS

Inspect all Reusable Accessories prior to use. DO NOT use if device damage is detected.

7.0 POTENTIAL COMPLICATIONS AND ADVERSE EVENTS

The following ANTICIPATED EVENTS have been identified as possible complications of the MitraClip™ G4 procedure.

- | | |
|---|--|
| <ul style="list-style-type: none"> • Allergic reactions or hypersensitivity to latex, contrast agent, anaesthesia, device materials (nickel / titanium, cobalt, chromium, polyester), and drug reactions to anticoagulation, or antiplatelet drugs • Vascular access complications which may require transfusion or vessel repair including: <ul style="list-style-type: none"> o wound dehiscence, o catheter site reactions, o Bleeding (including ecchymosis, oozing, hematoma, hemorrhage, retroperitoneal hemorrhage), o Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation / rupture, vascular occlusion o Emboli (air thrombotic material, implant, device component) o Peripheral Nerve Injury • Lymphatic complications • Pericardial complications which may require additional intervention, including: <ul style="list-style-type: none"> o Pericardial effusion o Cardiac tamponade o Pericarditis • Cardiac complications which may require additional interventions or emergency cardiac surgery, including: <ul style="list-style-type: none"> o Cardiac perforation o Atrial septal defect • Mitral valve complications, which may complicate or prevent later surgical repair, including: <ul style="list-style-type: none"> o Chordal entanglement / rupture o Single Leaflet Device Attachment (SLDA) o Thrombosis o Dislodgement of previously implanted devices o Tissue damage o Mitral valve stenosis o Persistent or residual mitral regurgitation o Endocarditis | <ul style="list-style-type: none"> • Cardiac arrhythmias (including conduction disorders, atrial arrhythmias, ventricular arrhythmias) • Cardiac ischemic conditions (including myocardial infarction, myocardial ischemia, and unstable / stable angina) • Venous thromboembolism (including deep vein thrombosis, pulmonary embolism, post procedure pulmonary embolism) • Stroke / Cerebrovascular accident (CVA) and Transient Ischemic Attack (TIA) • System organ failure: <ul style="list-style-type: none"> o Cardio-respiratory arrest o Worsening heart failure o Pulmonary congestion o Respiratory dysfunction / failure / atelectasis o Renal insufficiency or failure o Shock (including cardiogenic and anaphylactic) • Blood cell disorders (including coagulopathy, hemolysis, and Heparin Induced Thrombocytopenia (HIT)) • Hypotension / hypertension • Infection including: <ul style="list-style-type: none"> o Urinary Tract Infection (UTI) o Pneumonia o Septicemia • Nausea / vomiting • Chest pain • Dyspnea • Edema • Fever or hyperthermia • Pain • Death • Fluoroscopy, Transesophageal echocardiogram (TEE) and Transthoracic echocardiogram (TTE) -related complications: <ul style="list-style-type: none"> o Skin injury or tissue changes due to exposure to ionizing radiation o Esophageal irritation o Esophageal perforation o Gastrointestinal bleeding |
|---|--|

8.0 PATIENT COUNSELING AND PROVIDING INFORMATION TO THE PATIENT

Patients undergoing any procedures known to potentially be associated with bacteremia after implantation of the MitraClip™ G4 Implant should be prescribed prophylactic antibiotic therapy prior to such procedures.

Short-term anticoagulation therapy may be necessary after mitral valve repair with the MitraClip™ G4 Implant. Prescribe anticoagulation and other medical therapy per institutional guidelines.

All patients should be advised to limit strenuous physical activity for at least the first month post-procedure or longer if warranted.

Physicians should consider the following in counseling patients about the MitraClip™ G4 Implant:

- Discuss the risks associated with MitraClip™ G4 Implant placement.
- Discuss the risk / benefit considerations for the patient.

The following patient materials are included along with this product and shall be provided to the patient:

A Patient Implant Card (provided in package) which shall include:

- Patient information (supplied by the physician).
- Implant information (Physician to apply label peel away to Implant Patient Card).
- An Abbott Vascular website link to allow for rapid access to additional information regarding the device, including warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions.

9.0 HOW SUPPLIED

9.1 Contents

Clip Delivery System contents:

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

Steerable Guide Catheter contents:

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

9.2 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 the patient.

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

9.3 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.

10.0 STORAGE

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

11.0 MITRACLIP™ G4 SYSTEM DIMENSIONS

Table 1: MitraClip™ G4 System Dimensions

Component	Dimension			
Delivery Catheter				
Extended Length (from Sleeve curved at 90 degrees)	> 65 mm			
Steerable Sleeve				
Working Length	109.5 cm			
Catheter Distal Shaft Outer Diameter	5.3 mm (16 Fr)			
MitraClip™ G4 Implant	Clip Sizes			
	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 1E, Figures 2D 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)			

Figure 1: MitraClip™ G4 NT and NTW Implant Dimensions

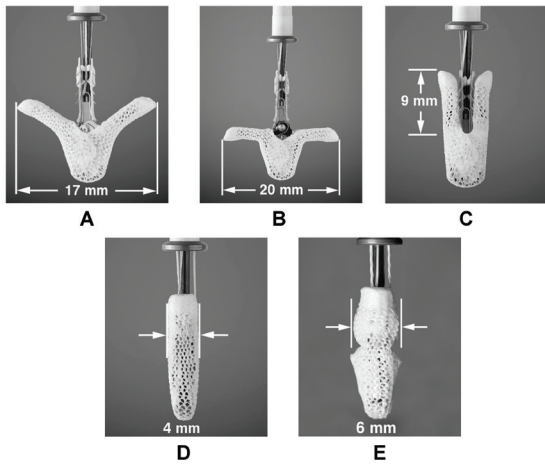
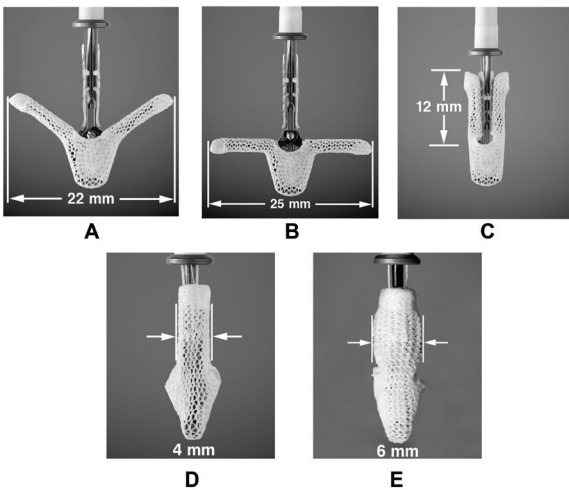


Figure 2: MitraClip™ G4 XT and XTW Implant Dimensions



The Clip Delivery System (Figures 4 and 5) is used to advance and manipulate the implantable MitraClip™ G4 Implant for proper positioning and placement on the mitral valve leaflets. The Clip Delivery System is designed to deploy the Implant in a way that requires multiple steps to ensure safe delivery of the device.

The outer surfaces of the Delivery Catheter and the Steerable Guide Catheter have a hydrophilic coating. The coatings are intended to decrease friction during insertion into the vasculature (Steerable Guide Catheter) and decrease friction between the Steerable Sleeve and the Delivery Catheter.

The MitraClip™ G4 Implant (Figure 6) is a percutaneously implanted mechanical Clip. There are four Implant sizes in the MitraClip™ G4 product family (G4 NT, G4 XT, G4 NTW, G4 XTW). The MitraClip™ G4 Implant grasps and coapts the mitral valve leaflets resulting in fixed approximation of the mitral leaflets throughout the cardiac cycle. The MitraClip™ G4 Implant is placed without the need for arresting the heart or cardiopulmonary bypass. The implantable MitraClip™ G4 Implant is manufactured with metal alloys and polyester fabric (Clip cover) that are commonly used in cardiovascular implants.

The MitraClip™ G4 Implant Arms can be adjusted to any position from fully opened, fully inverted and fully closed. These positions are designed to allow the MitraClip™ G4 Implant to grasp and approximate the leaflets of the mitral valve using controls on the Delivery Catheter Handle. The MitraClip™ G4 Implant can be locked, unlocked and repeatedly opened and closed. The Grippers can be raised or lowered repeatedly, either simultaneously or independently.

The MitraClip™ G4 Implant can be removed using standard surgical techniques and can be disposed of according to institutional guidelines.

The Steerable Guide Catheter (Figure 3a) is used to introduce the Clip Delivery System into the left side of the heart through the interatrial septum. The Steerable Guide Catheter is also used to position and orient the Clip Delivery System to the appropriate location above the mitral valve. The Steerable Guide Catheter can also be attached to a fluid filled pressure monitoring system (not provided) to measure left atrial pressures. The Dilator (Figure 3b) is used for the introduction of the Steerable Guide Catheter into the femoral vein and left atrium.

13.1 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™ G4 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.

13.2 Reusable Accessories Overview

Several accessories are used in conjunction with the MitraClip™ G4 System including: 1) a Stabilizer, 2) a Lift, 3) a Support Plate, 4) a Silicone Pad, and 5) Fasteners. The Stabilizer is provided separately as a non-sterile reusable device and must be cleaned and sterilized prior to each use. The Stabilizer is used on the sterile field to support and position the Steerable Guide Catheter and Clip Delivery System during the procedure. The Lift and Support Plate are provided separately as non-sterile reusable devices and must be cleaned prior to each use. The Lift and Support Plate are used outside the sterile field to provide a stable platform for the Stabilizer and MitraClip™ G4 System during the procedure. Follow the cleaning and sterilization instructions provided with the Stabilizer, Support Plate and Lift. The Silicone Pad and Fasteners are single use accessories and are provided sterile with the Steerable Guide Catheter packaging. The Silicone Pad is used on the sterile field under the Stabilizer to prevent incidental movement of the Stabilizer during the procedure. The Fasteners are used on the sterile field to secure the Steerable Guide Catheter and Clip Delivery System to the Stabilizer.

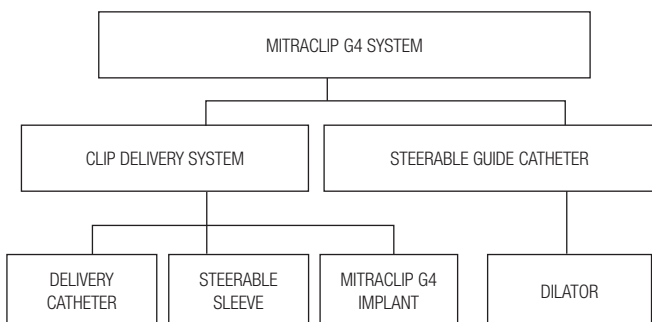
12.0 GLOSSARY OF ACRONYMS

Guide:	Steerable Guide Catheter	RA:	Right Atrium
CDS:	Clip Delivery System	LA:	Left Atrium
Sleeve:	Steerable Sleeve	LV:	Left Ventricle
DC:	Delivery Catheter	RO:	Radiopaque
Clip:	MitraClip™ G4 Implant	MR:	Mitral Regurgitation

13.0 DEVICE DESCRIPTION

The MitraClip™ G4 System consists of two parts: 1) the Clip Delivery System and 2) the Steerable Guide Catheter.

The Clip Delivery System consists of three major components: 1) the Delivery Catheter 2) the Steerable Sleeve and 3) the MitraClip™ G4 Implant. The Clip Delivery System is introduced into the body through a Steerable Guide Catheter which includes a dilator. The Clip Delivery System and Steerable Guide Catheter constitute the MitraClip™ G4 System.



Legend of Figure Labels

Figure 3a: Steerable Guide Catheter

- 1 Hemostasis Valve
- 2 Alignment Marker
- 3 Flush Port
- 4 +/- Knob
- 5 Proximal Shaft
- 6 Distal Shaft
- 7 Radiopaque Tip Ring

Figure 3b: Dilator

- 8 Rotating Hemostatic Valve
- 9 Flush Port
- 10 Echogenic Spiral Groove

- 21 Sleeve Flush Port
- 22 A/P Knob
- 23 M/L Knob
- 24 Steerable Sleeve Handle

Figure 5: CDS Distal End

- 25 Longitudinal Alignment Marker
- 26 Key
- 27 Steerable Sleeve Shaft
- 28 Radiopaque Alignment Markers
 - 28a Proximal
 - 28b Distal
- 29 Sleeve Radiopaque Tip Ring
- 30 Delivery Catheter Shaft
- 31 Delivery Catheter Radiopaque Ring
- 32 MitraClip™ G4 Implant

Figure 6: MitraClip™ G4 Implant Device Positions

- A Clip fully closed (low profile)
- B Clip at 180 degrees
- C Clip at 120 degrees
- D Clip at 60 degrees
- E Clip at 20 degrees
- F Clip fully inverted

Figure 4: CDS Handles

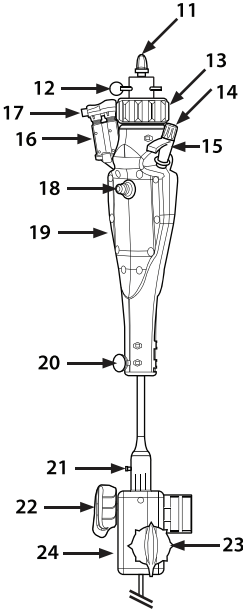


Figure 5: CDS Distal End

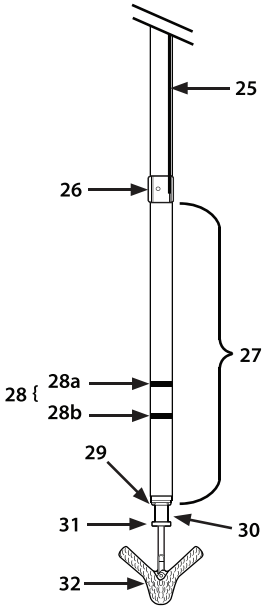


Figure 3a: Steerable Guide Catheter

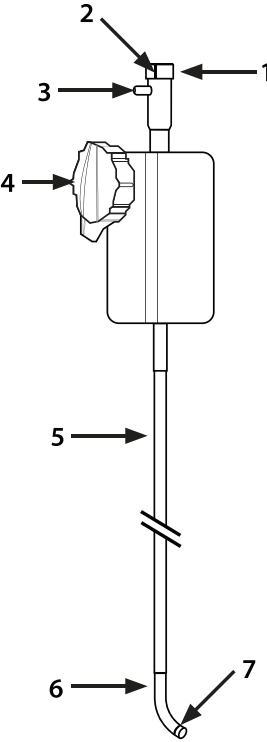


Figure 3b: Dilator

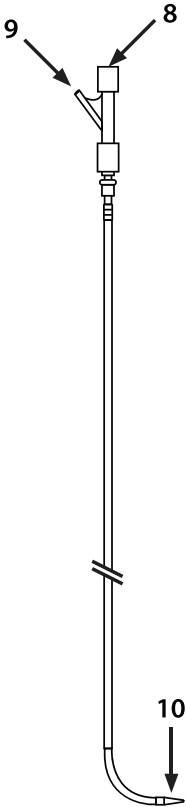
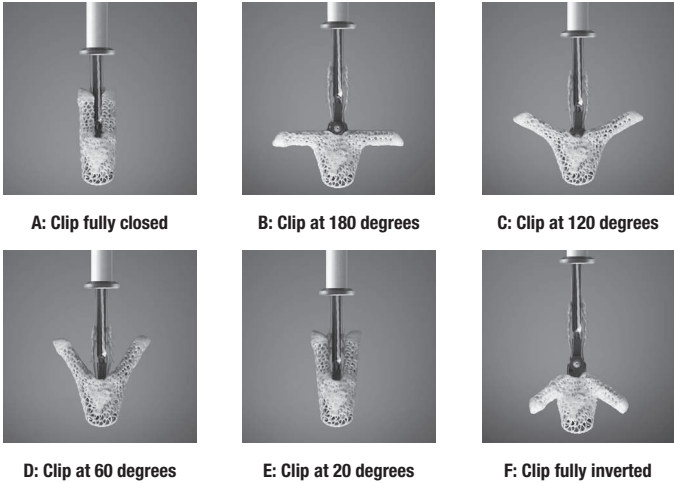


Figure 6: MitraClip™ G4 Implant Positions



The Steerable Guide Catheter and Clip Delivery System (Steerable Sleeve, Delivery Catheter and Clip) are steered and actuated by the use of control knobs, levers and fasteners located on the handles.

Table 2: MitraClip™ System Handle Controls

Device	Control	Function
Steerable Guide Catheter	+/- Knob	Tip deflection
Steerable Sleeve	M/L Knob A/P Knob	Tip deflection Tip deflection
Delivery Catheter	Lock Lever Gripper Levers Arm Positioner DC Fastener Lock Lever Cap Release Pin Actuator Knob	Locks-Unlocks Clip Raises-Lowers Grippers Opens-Closes Clip Arms Locks-Unlocks DC translation / torque Controls removal of Lock Line Prevents Actuator Knob turning Rotates for Clip deployment

14.0 REQUIRED ACCESSORIES

- SZR01: One (1) Stabilizer
- LFT01: One (1) Lift
- PLT01: One (1) Support Plate
- One (1) Silicone Pad, three (3) Fasteners (All are included sterile with the Steerable Guide Catheter)

15.0 ADDITIONAL REQUIRED EQUIPMENT NOT INCLUDED

Transseptal sheath and guidewire
Transseptal needle
Exchange length supportive 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

16.0 MITRACLIP™ G4 PROCEDURE STEP-BY-STEP INSTRUCTIONS

16.1 DEFINITION OF TERMS

Defined Terms are in italics throughout document.

TERM	DEFINITION AND RELATED TECHNIQUE
<i>Lock the Clip</i>	<ol style="list-style-type: none">1. Rotate the Lock Lever outward.2. Fully advance the Lock Lever.3. Rotate the Lock Lever inward to engage the lever.
<i>Unlock the Clip</i>	<ol style="list-style-type: none">1. Rotate the Lock Lever outward and then retract the lever until the mark on the lever is fully exposed.2. Rotate the Lock Lever inward to engage the lever.
<i>Open the Clip Arms</i>	<ol style="list-style-type: none">1. Confirm the Clip is unlocked.2. Turn the Arm Positioner at least 1/2 turn in the "Close" (clockwise) direction.3. Turn the Arm Positioner in the "Open" (counter-clockwise) direction until the desired <i>Clip Arm Angle</i> is achieved. NOTE 1: If Clip does not open smoothly, retract the Lock Lever farther, then repeat steps 2 – 3. NOTE 2: If the Clip Arms fail to open visibly (as observed under fluoroscopic guidance), use the following techniques in the order provided, as needed:<ol style="list-style-type: none">A. Stop and return <i>Arm Positioner to Neutral</i>. Retract Lock Lever farther, then turn the Arm Positioner farther in the "Close" direction before turning in the "Open" direction. Advance the lock lever just enough so that the mark on the lever is still fully exposed.B. Turn the <i>Arm Positioner to Neutral</i>, then incrementally iterate the amount of Arm Positioner rotation in the "Close" direction followed by rotation in the "Open" direction. Iterate until Clip opens or until it is no longer possible to rotate the Arm Positioner in the "Close" direction. Advance the lock lever just enough so that the mark on the lever is still fully exposed.C. Turn the <i>Arm Positioner to Neutral</i>, iterate the amount of Lock Lever retraction past the mark in 5 mm increments, and rotate the Arm Positioner fully in the "Close" direction, before rotating in the "Open" direction, until Clip opens. Advance the lock lever just enough so that the mark on the lever is still fully exposed.D. Advance the Gripper Lever and repeat NOTE 2, Step C. Retract the Gripper Lever after Clip opens.E. If in the LA and free of tissue, release the DC Fastener, then release the Sleeve curves and repeat NOTE 2, Step C. WARNING: Do release the DC Fastener before releasing Sleeve curves, otherwise it may result in device damage and / or device or component embolization.F. If the Clip does not open after performing all steps in NOTE 2, DO NOT use the device.
<i>Arm Positioner to Neutral</i>	Turn the Arm Positioner in the "Close" or "Open" direction until no resistance to turning is noted.
<i>Invert the Clip Arms</i>	<ol style="list-style-type: none">1. Confirm the Clip is unlocked.2. Turn the Arm Positioner at least 1/2 turn in the "Close" direction.3. Turn the Arm Positioner in the "Open" direction until a <i>Clip Arm Angle</i> of 180° is observed under fluoroscopic guidance. Note the orientation of the blue line on the Arm Positioner.4. Continue turning the Arm Positioner in the "Open" direction until the Clip Arms invert, no more than 1 full turn from 180°. DO NOT over-invert the Clip Arms. DO NOT turn Arm Positioner more than 1 full turn past a <i>Clip Arm Angle</i> of 180° or past when resistance is first noted. WARNING: Turning the Arm Positioner in the "Open" direction more than 1 full turn past a <i>Clip Arm Angle</i> of 180° or turning past when resistance is first noted may result in device damage which could cause the Clip to become non-functional and lead to embolization, and / or conversion to surgical intervention.
<i>Raise the Gripper(s)</i>	<ol style="list-style-type: none">(a) Simultaneously - Confirm Gripper Levers are latched. Slowly retract the Gripper Levers until a hard stop is reached (under fluoroscopic and echocardiographic observation). or(b) Independently - Unlatch the Gripper Levers and slowly retract the desired Gripper Lever until a hard stop is reached (under fluoroscopic and echocardiographic observation). Re-latch the Gripper Levers.

TERM	DEFINITION AND RELATED TECHNIQUE
<i>Lower the Gripper(s)</i>	<ol style="list-style-type: none">(a) Simultaneously - Confirm the Gripper Levers are latched and fully advance the Gripper Levers. or(b) Independently - Unlatch the Gripper Levers and fully advance the desired Gripper Lever(s). Re-latch the Gripper Levers.
<i>Identify Gripper Orientation</i>	<ol style="list-style-type: none">1. Unlatch the Gripper Levers.2. Advance and retract the Gripper Lever with the tactile marker under imaging (echocardiography) to identify Gripper Lever to the corresponding leaflet.3. Once Gripper(s) are identified, Raise the Gripper(s) until ready for leaflet capture.
<i>Clip Arm Angle</i>	<ul style="list-style-type: none">• Angle between the inner edges of both Clip Arms.• All <i>Clip Arm Angles</i> are measured using fluoroscopy with optimal view allowing clear observation of the tip of the Clip and both arms in the same plane so they appear as a "V" (see Figure 6).
<i>Grasping Arm Angle</i>	A <i>Clip Arm Angle</i> of approximately 120 degrees.
<i>Fully Close the Clip Arms</i>	Turn the Arm Positioner in the "Close" direction until the Clip Arms contact the DC. <ul style="list-style-type: none">• Under direct visualization, the Clip is fully closed when the Clip Covering contacts the DC.• Under fluoroscopic observation, the Clip is fully closed when the inner edges of the Clip Arms are parallel.
<i>Establish Final Arm Angle</i>	Verification step to confirm that the pre-deployment <i>Clip Arm Angle</i> will reflect the <i>Clip Arm Angle</i> post-deployment. <ol style="list-style-type: none">1. With the Lock Lever fully advanced, and the <i>Arm Positioner to Neutral</i> (note the orientation of the blue line on the Arm Positioner), turn the Arm Positioner 1 turn in the "Open" direction (confirm blue line has returned to the original orientation). The Clip Arms may open slightly (~5°) and then remain in a stable position. NOTE: If continued opening of the Clip Arms is noted, reconfirm that the Lock Lever is completely advanced. Close the Clip Arms, and <i>Establish Final Arm Angle</i>. WARNING: DO NOT turn the Arm Positioner more than 1 turn in the "Open" direction from neutral. Failure to stop turning the Arm Positioner at 1 turn in the "Open" direction past neutral may result in Clip opening or device damage which could cause the Clip to become non-functional and lead to embolization and / or conversion to surgical intervention.
<i>Left Atrial Pressure Capability</i>	If using left atrial pressure capability, connect a fluid filled pressure monitoring system (not supplied) to the luer port of the Guide valve housing. Calibrate the pressure monitoring system and obtain measurements via the manufacturer's instructions for use. NOTE: Ensure no bubbles are present after inserting the CDS into the Guide. When measuring left atrial pressure, ensure the Clip is not obstructing the Guide Lumen, the Guide RO Tip Ring is between the RO Alignment Markers of the Sleeve, and the Sleeve is not deflected more than 90 degrees as this may impair Guide lumen patency.

17.0 PATIENT PREPARATION

- 17.1 Prepare the patient per institution's standard practice for transseptal catheterization.
- 17.2 Place support plate under patient's leg in the region between the area of the upper leg and the knee and place the Lift over the ipsilateral lower extremity prior to draping the patient.
- 17.3 Place the Lift on the Support Plate such that the front edge (i.e., the edge that corresponds with the shorter legs of the Lift) is approximately 80 cm from the patient's mid sternum.
- 17.4 Adjust the height of the Lift so that the front edge of the Lift is close to the patient's leg but is not impinging on it. Adjust the back legs to be 2 or 3 notches above the front legs (i.e., the back legs of the Lift are taller than the front legs).

CAUTION: Ensure the Lift and Support Plate are covered completely by sterile drape during the procedure. Use towels as necessary to minimize direct contact between the patient and all surfaces of both the Lift and Support Plate.

- 17.5 Prepare the patient for invasive hemodynamic monitoring.

18.0 MITRACLIP™ G4 SYSTEM PREPARATION BEFORE USE

WARNING: DO NOT use the MitraClip™ G4 System after the "Use By" date stated on the package label, and never reuse or re-sterilize the system. Use of expired, reused, or re-sterilized devices may result in infection.

WARNING: Always inspect the MitraClip™ G4 System and its packaging to verify no damage has occurred as a result of shipping and handling and that the sterile barrier has not been compromised. DO NOT use the device if damage is detected. Use of product with a compromised sterile barrier may result in infection. Use of damaged product may result in patient injury.

- DO NOT remove the protective cover placed over the Clip.

WARNING: DO NOT handle the Clip directly; leave it in the protective cover to avoid potential contamination. Removal of the protective cover may result in infection. Removal of the protective cover may result in damaged product which may result in patient injury.

- The preparation is most easily accomplished with the aid of an assistant.

18.1 Steerable Guide Catheter Preparation

WARNING: All lumens contain air when shipped. Use proper de-airing techniques before and during use to minimize the risk of air embolism.

- 18.1.1 Carefully remove the white Guide tip shape retainer and transparent protective tubing from the Guide tip.
- 18.1.2 Inspect Steerable Guide Catheter and Dilator to verify they are undamaged.
- WARNING: DO NOT use if damage is detected. Use of damaged product may result in air embolism, vascular and / or cardiac injury.**
- 18.1.3 Remove the sterile package containing Fasteners and Silicone Pad from the Steerable Guide Catheter tray.
- 18.1.4 Fill a basin with heparinized saline.
- 18.1.5 Flush and de-air the Guide and Dilator with heparinized saline:
- 18.1.5.1 Connect 3-way stopcocks to the Guide and Dilator flush ports, de-air the Dilator, and close the stopcock and the Rotating Hemostatic Valve.
- 18.1.5.2 Hydrate 5-10 cm of the distal end of the Dilator with heparinized saline and insert the Dilator approximately 10 cm into Guide then remove.
- 18.1.5.3 Connect high pressure tubing and a 50–60 cc syringe filled with heparinized saline to the Guide flush port.
- 18.1.5.4 De-air the Guide.
- 18.1.5.4.1 With the tip raised, displace all air from the Guide while tapping along the length of the catheter shaft.
- 18.1.5.4.2 Cover the Guide tip with finger once heparinized saline exits the Guide.
- 18.1.5.4.3 Close the Guide stopcock.
- 18.1.6 Submerge the Guide tip in the basin of heparinized saline.
- 18.1.7 While the Guide tip is submerged in the basin of heparinized saline, remove finger from Guide tip and check the Guide valve for leaks by raising the handle to a vertical position for a minimum of 30 seconds.
- 18.1.8 Hydrate 5-10 cm of the distal end of the Dilator with heparinized saline.
- 18.1.9 Cover the Guide tip with finger and insert the Dilator into the Guide while Guide tip remains submerged in the basin of heparinized saline.
- 18.1.9.1 While advancing the Dilator, continually watch for air in the Guide Hemostasis Valve housing. If needed, remove finger from Guide tip and aspirate while assuring the Guide tip is submerged.
- 18.1.10 Remove finger from tip of Guide when the Dilator tip approaches the Guide tip.
- 18.1.11 Position the Dilator to create a smooth transition.

18.2 Stabilizer Preparation

Assemble the sterilized Stabilizer. Set the Stabilizer aside in a protected sterile environment for later use.

18.3 Clip Delivery System Preparation

- 18.3.1 Release the DC Fastener and rotate the DC Handle 90 degrees clockwise when the CDS is removed from packaging. Secure the DC Fastener.
- 18.3.2 Inspect all Clip Delivery System parts, including the Clip, DC shaft, and Sleeve to verify they are undamaged.

WARNING: DO NOT use the device if damage is detected. Use of damaged product may result in air embolism, Implant or device component embolization, vascular and / or cardiac injury.

Sleeve Preparation

- 18.3.3 Connect 3-way stopcocks to the Sleeve flush port and bottom DC flush port.
- 18.3.4 Remove the cap from the Clip Introducer and place the cap on the top flush port of the DC Handle.
- 18.3.5 Connect a 3-way stopcock to the Clip Introducer flush port.
- 18.3.6 Attach a 50-60 cc syringe filled with heparinized saline to the 3-way stopcock on the Clip Introducer, de-air the Clip Introducer, and close the stopcock.
- 18.3.7 Connect one high pressure tube to each drip line from the pressurized bags with sterile heparinized saline; flush and de-air the lines.
- 18.3.8 Connect one high pressure tube to the 3-way stopcock on the bottom flush port of the DC Handle and one high pressure tube to the 3-way stopcock on the flush port of the Sleeve Handle.
- 18.3.9 Flush and de-air the Sleeve with heparinized saline.
- 18.3.9.1 While flushing, release the DC Fastener, retract and advance the DC Handle to remove residual air from the lumen.

WARNING: DO NOT use excessive force when pulling the DC (Delivery Catheter) Radiopaque Ring against the Sleeve tip, while translating the DC shaft. It may result in device damage including distal tip embolization.

- 18.3.10 Secure the DC Fastener with DC Handle fully advanced.

Delivery Catheter Preparation

CAUTION: DO NOT handle the Clip directly; leave in the protective cover to avoid potential contamination. Removal of the protective cover may result in damaged product which may result in patient injury.

- 18.3.11 Temporarily remove the cap from top flush port of the DC Handle to flush and de-air DC Handle and all lumens of the DC with heparinized saline.
- 18.3.12 After de-airing the DC Handle chamber, replace the cap to close off top flush port of the DC Handle.
- 18.3.13 Retract and advance the Lock Lever several times to remove residual air from the lumens.

WARNING: DO NOT retract the Lock Lever forcefully. It may result in the inability to lock or unlock the Clip. Damage could occur causing the Clip to not unlock or open. Inability to open the Clip may result in valve injury or lead to deployment of the Clip in an unintended location.

- 18.3.14 Loosen the Lock Lever Cap to de-air. DO NOT turn Lock Lever Cap more than 1/2 turn in the "Open" direction. After de-airing, tighten the Lock Lever Cap.
- 18.3.15 With the tip raised and the shaft held taut, displace all air from the DC and Sleeve while tapping along the length of the catheter shaft.
- 18.3.16 Confirm continuous flow from the distal end of the DC and Sleeve.

Delivery Catheter and Clip Inspection

WARNING: DO NOT handle the Clip directly, leave in the protective cover to avoid potential contamination. Removal of the protective cover may result in infection. Removal of the protective cover may result in damaged product which may result in patient injury.

- 18.3.17 *Raise the Gripper(s), Unlock the Clip, and confirm the Clip is at Grasping Arm Angle.*
- NOTE:** If *Clip Arm Angle* is greater than *Grasping Arm Angle*, close the Clip to *Grasping Arm Angle*; if *Clip Arm Angle* is less than *Grasping Arm Angle*, *Open the Clip Arms to Grasping Arm Angle*.
- 18.3.18 *Lower the Gripper(s)* once to de-air the lumens.
- 18.3.19 Close the Clip Arms to approximately 60 degrees and *Lock the Clip*.
- 18.3.20 Close the Clip Arms to approximately 20 degrees and *Establish Final Arm Angle*.

WARNING: DO NOT turn the Arm Positioner more than 1 turn in the "Open" direction from neutral. Failure to stop turning the Arm Positioner at 1 turn in the "Open" direction past neutral may result in Clip opening or device damage which could cause the Clip to become non-functional and lead to embolization and / or conversion to surgical intervention.

- 18.3.21 *Return the Arm Positioner to Neutral.*
- 18.3.22 *Raise the Gripper(s), Unlock the Clip, and Invert the Clip Arms.*

WARNING: DO NOT retract the Lock Lever forcefully. It may result in the inability to lock or unlock the Clip. Damage could occur causing the Clip to not unlock or open. Inability to open the Clip may result in valve injury or lead to deployment of the Clip in an unintended location.

WARNING: Turning the Arm Positioner in the "Open" direction more than 1 full turn past a *Clip Arm Angle* of 180° or turning past when resistance is first noted may result in device damage which could cause the Clip to become non-functional and lead to embolization, and / or conversion to surgical intervention.

- 18.3.23 *Lock the Clip, Fully Close the Clip Arms, and Lower the Gripper(s).*
- 18.3.24 Release the DC Fastener and torque the DC Handle clockwise and counter-clockwise ¼ turn while translating the shaft.
- 18.3.25 Retract the DC fully against the sleeve and secure the DC Fastener.

WARNING: Do not use excessive force when pulling the DC (Delivery Catheter) Radiopaque Ring against the Sleeve tip while translating the DC shaft. It may result in device damage including distal tip embolization.

- 18.3.26 Without removing the protective cover, carefully slide the Clip Introducer over the Clip and stop when the tip of the Clip is just proximal to the tip of the Clip Introducer.

WARNING: DO NOT compress the Clip Arms. Compressing the Clip Arms may result in inability to open the Clip. Inability to open the Clip may result in valve injury or lead to deployment of the Clip in an unintended location.

WARNING: Fully Close the Clip Arms before insertion or retraction into the Clip Introducer. Failure to do so may result in difficulty or inability to advance or retract the Clip, which may result in vascular and / or cardiac injury, air embolism, and / or the need for surgical intervention.

- 18.3.27 *Return the Arm Positioner to Neutral.*
- 18.3.28 Temporarily discontinue heparinized saline flushes.
- 18.3.29 Re-start heparinized saline flushes just before the use of CDS.

WARNING:

- Heparinized saline flush should be continuous throughout the procedure.
- Discontinuing flush may result in air embolism and / or thrombus formation.
- Ensure flow is visible through the drip chamber and that the tubing is free from kinks and / or obstruction.
- Ensure pressure of 300 mmHg is maintained.

19.0 ACCESS TO THE MITRAL VALVE

NOTE: This is a suggested sequence for the procedure. Variations may be used based upon patient anatomy.

- 19.1 Access the LA to accommodate the Guide tip using transvenous, transseptal techniques and equipment.
- 19.2 Heparinize the patient.

WARNING: Failure to administer heparin once transseptal access has been achieved may result in thrombus formation.

- 19.3 Carefully place an exchange length supportive guidewire in the left upper pulmonary vein or LA. Dilate the subcutaneous tissue and femoral vein to accommodate the Guide shaft using standard dilation technique.

20.0 STEERABLE GUIDE CATHETER INSERTION

WARNING: Confirm a smooth transition between the Dilator and the tip of the Guide to minimize the risk of vascular and / or cardiac injury.

CAUTION: Always use pressure monitoring, echocardiography and fluoroscopy for guidance and observation during use of the MitraClip™ G4 System.

WARNING: Always use a careful, deliberate, and iterative approach to positioning the MitraClip™ G4 System. It is recommended to make multiple small adjustments rather than single large adjustments. Large adjustments may result in vascular and / or cardiac injury.

- 20.1 Rotate the +/- Knob in the "-" direction until the Guide curve is substantially straightened.
- 20.2 Wet the surface of the Guide shaft with sterile saline.
- 20.3 Insert the Guide-Dilator assembly over the stationary guidewire into the femoral vein.

WARNING: DO NOT use excessive force to advance or manipulate the Guide-Dilator assembly. If resistance is encountered, use echocardiography and / or fluoroscopy to assess before proceeding. Use of excessive force may result in arrhythmias, vascular and / or cardiac injury, including creation of a clinically significant atrial septal defect.

- 20.4 Advance the Guide-Dilator assembly to the RA. Rotate the +/- Knob to Neutral, then place tip of the Dilator partially across the atrial septum.
- 20.5 Slowly dilate the atrial septum by gradually advancing the tip of the Guide-Dilator assembly.

WARNING: DO NOT rapidly advance the Guide-Dilator assembly across the atrial septum. Rapid advancement may result in vascular and / or cardiac injury.

- 20.6 Advance the Guide-Dilator assembly until the tip of the Guide extends approximately 3 cm in the LA.
- 20.7 Adjust Guide deflection and torque to position the tip away from adjacent tissues.
- 20.8 Place the Silicone Pad on the sterile drape over the Lift. Place the Stabilizer onto the Silicone Pad.
- 20.9 Secure the Guide in the Stabilizer slot using the Fastener. Ensure the Fastener engages the metallic tube on the Guide shaft. The Guide handle should be immediately adjacent to the Stabilizer, such that they are in contact with each other.
- 20.10 Retract the Dilator approximately 5 cm into the Guide, leaving the guide wire in the left upper pulmonary vein or LA.

CAUTION: Always loosen the Fastener before torquing the Guide to prevent stripping the screw.

- 20.11 Retract the guidewire into the tip of the Dilator. Remove the Dilator and guidewire while gently aspirating the Guide (starting when the Dilator is approximately halfway retracted into the Guide, approximately 40 cm) using a 50–60 cc syringe. Cover Guide Hemostasis Valve with finger upon Dilator removal.

NOTE: Avoid contacting tissue or creating a vacuum in the Guide lumen. If necessary, position the Guide handle below the level of the LA to allow blood to fill the Guide lumen.

WARNING: DO NOT create a vacuum while removing the dilator from the Guide; air may enter the lumen of the Guide which may result in air embolism.

WARNING: Failure to fully retract guidewire into the Dilator may result in air embolism.

21.0 CLIP DELIVERY SYSTEM INSERTION

- 21.1 Confirm the Guide lumen is completely de-aired.

WARNING: To minimize the potential of air embolism, DO NOT introduce the CDS into the Guide until the Guide lumen has been completely de-aired.

- 21.2 Confirm there is a slow, continuous heparinized saline flush through both the Sleeve and the DC and that the tip of the Clip is just proximal to the tip of the Clip Introducer.

CAUTION: Failure to continuously flush the CDS with heparinized saline may reduce device performance.

WARNING:

- Heparinized saline flush should be continuous throughout the procedure.
- Discontinuing flush may result in air embolism and / or thrombus formation.
- Ensure flow is visible through the drip chamber and that tubing is free from kinks and / or obstruction.
- Ensure pressure of 300 mmHg is maintained.

- 21.3 Carefully remove the protective cover surrounding the Clip and the Clip Introducer.

- 21.4 Confirm that the stopcock on the Clip Introducer flush port is closed and that the Clip Introducer is de-aired.

- 21.5 While flushing heparinized saline on the Guide Hemostasis Valve, place the tip of the Clip Introducer against the Guide Hemostasis Valve and advance the Clip Introducer straight into the valve in a continuous motion while rotating the Clip Introducer in small clockwise and counterclockwise motions until the Clip can be observed distal to the valve.

WARNING: DO NOT continue to advance the Clip Introducer if resistance is felt; the Guide Hemostasis Valve, Clip Introducer or the Clip may be damaged. Damage to these components may result in air embolism, vascular or cardiac injury.

WARNING: To minimize the potential of air embolism, ensure proper de-airing when inserting the Clip Introducer into the Guide Hemostasis Valve.

- 21.6 Leave the Clip Introducer fully inserted in the Guide Hemostasis Valve throughout the procedure.

- 21.7 Align the Longitudinal Alignment Marker on the Sleeve shaft with the Alignment Marker on the Guide Hemostasis Valve.

- 21.8 Turn the +/- Knob to neutral then carefully advance the CDS through the Guide under fluoroscopic guidance. Stop when tip of the Clip is even with the tip of the Guide.

NOTE: If resistance to CDS advancement is felt, reduce Guide deflection.

- 21.9 Under echocardiographic guidance, advance the CDS and retract the Guide iteratively as needed while maintaining the Guide in the LA. Stop when the Guide RO Tip Ring is between the RO Alignment Markers of the Sleeve, as confirmed under fluoroscopic guidance.

- 21.10 Position the Sleeve Handle in the Stabilizer slot.

- 21.11 Confirm that the Clip is free from the left atrial wall and valve tissue.

WARNING: Failure to confirm that the Clip is free from the left atrial wall and valve tissue may result in cardiac injury.

22.0 INITIAL MITRACLIP™ G4 SYSTEM POSITIONING IN THE LEFT ATRIUM

NOTE: Positioning is achieved with iterative adjustments of the Guide and CDS using torque, translation, and knob adjustments. The goals of positioning are:

- A. Positioning the Clip centrally over the valve with respect to anterior-posterior and medial-lateral directions.
- B. Aligning the Clip so the DC Shaft is perpendicular to the plane of the mitral valve.
- C. Positioning the distal tip of the Clip at least 1 cm above the leaflets.

WARNING: Excessive torque on the Guide and translation of the MitraClip™ G4 System may inadvertently displace the tip of the Guide from the LA, which may result in arrhythmias or cardiac injury.

WARNING: DO NOT continue to rotate or manipulate any of the knobs if significant resistance is noted; device damage may occur and result in cardiac injury.

- 22.1 Adjust the Guide position as necessary to maintain that the Clip is free from adjacent tissue.

- 22.2 Adjust Sleeve deflection using the M/L Knob and / or the A/P Knob to deflect the Clip towards the apex. Retract the DC Radiopaque Ring against the Sleeve tip as necessary.

- 22.3 During Sleeve deflections confirm that the Guide RO Tip Ring is between the RO Alignment Markers of the Sleeve prior to making maximum Sleeve deflections.

WARNING: DO NOT deflect the Sleeve tip more than 90 degrees as device damage may occur. Use of damaged product may result in cardiac injury.

- 22.4 Secure the Sleeve handle in the Stabilizer using the Fastener.

- 22.5 To reposition the MitraClip™ G4 System, move the Stabilizer with the system until positioning is adequate.

- 22.6 Adjust the MitraClip™ G4 System position to maintain adequate height above the mitral valve in the LA.

WARNING: Maintain the Clip above the leaflets until ready to grasp to minimize the risk of Clip entanglement in the chordal apparatus. Clip entanglement may result in cardiac injury, worsening mitral regurgitation, difficulty or inability to remove the Clip and conversion to surgical intervention.

23.0 FINAL MITRACLIP™ G4 SYSTEM POSITIONING

- 23.1 Raise the Gripper(s).

CAUTION: Raising the Gridders more often than needed or retracting the Gripper Lever forcefully may damage the Gripper cover or Gripper line and impair CDS performance.

- 23.2 Unlock the Clip and Open the Clip Arms to approximately 180 degrees.

WARNING: DO NOT RETRACT THE LOCK LEVER FORCEFULLY. Retracting the Lock Lever forcefully may result in the inability to unlock Clip. Inability to open the Clip may result in valve injury or lead to deployment of the Clip in an unintended location.

- 23.3 Adjust the MitraClip™ G4 System to reposition the Clip as necessary. Confirm that the distal tip of the Clip is at least 1 cm above the leaflets.

- 23.4 Rotate the DC handle to align the Clip Arms perpendicular to the line of coaptation. DO NOT rotate the Clip more than 90 degrees in each direction.

- 23.5 Carefully translate the DC shaft multiple times to release stored torque. Fully retract the DC.

WARNING: Fully release stored torque. If not done, it may result in unwanted Clip Arm orientation changes during grasping. Torque of the DC Handle more than 180 degrees may result in DC damage and cardiac injury.

- 23.6 Identify Gripper Orientation.

- 23.7 Close the Clip to a Clip Arm Angle of approximately 60 degrees.

- 23.8 Complete final MitraClip™ G4 System positioning in the LA using multiple imaging planes. Re-secure the Guide and Sleeve Fasteners as appropriate.

24.0 GRASPING THE LEAFLETS AND VERIFYING THE GRASP

- 24.1 Advance the DC distally to position the Clip approximately 2 cm below the valve. Ensure that the Clip Arms are oriented perpendicular to the line of coaptation.

WARNING: Do confirm that the Clip Arms are perpendicular to the line of coaptation. Failure to do so may result in loss of leaflet capture and insertion. Loss of leaflet capture and insertion may result in inadequate reduction of mitral regurgitation and may result in a single leaflet device attachment (SLDA).

	WARNING:	DO NOT make substantial Clip Arm orientation adjustment in the LV. Clip entanglement in chordae may result in cardiac injury and worsening mitral regurgitation; and may result in difficulty or inability to remove the Clip, and conversion to surgical intervention.	WARNING:	Turning the Arm Positioner in the “Open” direction more than 1 full turn past a <i>Clip Arm Angle</i> of 180° or turning past when resistance is first noted may result in device damage which could cause the Clip to become non-functional and lead to embolization, and / or conversion to surgical intervention.
	WARNING:	Always ensure that either the Grippers are raised or that the Clip is closed while in the LV to avoid potential cardiac injury.	25.3.2	Retract the inverted Clip into the LA.
24.2		<i>Open the Clip Arms to the Grasping Arm Angle.</i>	25.3.3	Confirm both leaflets move freely.
24.3		Without using excessive force, retract the DC to grasp the anterior and posterior leaflets.	25.3.4	Repeat positioning steps, as necessary, then repeat grasping steps.
	WARNING:	An improper grasp will allow one or both leaflets to move freely. Closing and deploying the Clip in this situation may result in loss of leaflet capture and insertion. Loss of leaflet capture and insertion may result in inadequate reduction of mitral regurgitation and may result in a single leaflet device attachment (SLDA).	26.0	MITRACLIP™ G4 IMPLANT PRE-DEPLOYMENT CLIP ASSESSMENT
24.4		If the grasp appears satisfactory, <i>Lower the Gripper(s)</i> onto the leaflets.	26.1	Confirm DC Handle is secure.
	NOTE:	Simultaneous leaflet capture with both Grippers should be attempted first. If unsuccessful, <i>Raise the Gripper(s)</i> to release leaflet capture and <i>Lower the Gripper(s)</i> to capture leaflets. Raising and lowering Gripper(s) can be done simultaneously or independently.	WARNING:	Do secure the DC Handle. If not done, it may result in leaflet injury or loss of leaflet insertion with resultant worsening mitral regurgitation, single leaflet device attachment (SLDA), and / or conversion to surgical intervention.
	WARNING:	DO NOT advance the DC handle or adjust the position of the MitraClip™ G4 System in a way that increases tension on the leaflets after grasping the leaflets, as valve injury may occur.	26.2	<i>Establish Final Arm Angle.</i>
			WARNING:	DO NOT turn the Arm Positioner more than 1 turn in the “Open” direction from neutral. Failure to stop turning the Arm Positioner at 1 turn in the “Open” direction past neutral may result in Clip opening or device damage which could cause the Clip to become non-functional and lead to embolization and / or conversion to surgical intervention.
24.4.1		If both Grippers have not lowered:	26.3	Turn the Arm Positioner to the “closed” side of the neutral position.
24.4.1.1		<i>Lock the Clip.</i>	26.4	Perform mean pressure gradient assessment prior to proceeding to deployment.
24.4.1.2		Confirm both Grippers have lowered.	27.0	CLIP DEPLOYMENT
24.4.1.3		<i>Unlock the Clip.</i>	27.1	Deployment Step 1: Lock Line Removal
	WARNING:	Failure to confirm that both Grippers have been lowered onto the leaflets prior to closing the Clip may result in loss of leaflet capture and insertion. Loss of leaflet capture and insertion may result in inadequate reduction of mitral regurgitation and may result in a single leaflet device attachment (SLDA).	27.1.1	While holding the ends of the Lock Line remove the Lock Lever Cap and “O” ring. Unwrap the two ends of the Lock Line in a counterclockwise direction. Separate the ends of the Lock Line and remove the plastic cover from the lines so that no twists or knots are present.
24.5		Close the Clip until the <i>Clip Arm Angle</i> is approximately 60 degrees. Release tension on the DC and secure the DC Fastener.	WARNING:	Do not let Line unravel freely. Do not remove Lock Line or plastic covers if line is bunched. Letting Line unravel freely may result in knots in the line. Removing Line if it is bunched may result in difficulty or inability to remove line due to knots or twists.
24.6		Use echocardiographic imaging to verify insertion of both leaflets and satisfactory grasp by observation of:	27.1.2	Grasp one of the free ends of the Lock Line, confirm the line moves freely, and slowly remove the Lock Line. Pull the Lock Line coaxial to the Lock Lever. If resistance is noted, stop and pull on the other free end to remove the Lock Line.
		<ul style="list-style-type: none"> • Leaflet immobilization • Single or multiple valve orifice(s) • Limited leaflet mobility relative to the tips of both Clip Arms • Adequate MR reduction 	27.1.3	<i>Establish Final Arm Angle.</i>
24.6.1		If grasping fails to hold both leaflets and the Clip retracts to the LA, reposition the MitraClip™ G4 System.	NOTE:	The Clip Arms may open slightly (~5°) and then remain in a stable position. If Arms open more than slightly, close the Clip to the desired Arm position and re- <i>Establish Final Arm Angle</i> .
24.6.1.1		<i>Open the Clip Arms</i> and reorient the Clip Arms in the LA, as needed, then repeat grasping steps (refer to Section 23.0 and 24.0).	WARNING:	DO NOT turn the Arm Positioner more than 1 turn in the “Open” direction from neutral. Failure to stop turning the Arm Positioner at 1 turn in the “Open” direction past neutral may result in Implant opening or device damage which could cause the Implant to become non-functional and lead to embolization and / or conversion to surgical intervention.
24.6.1.1.1		If significant repositioning is necessary, <i>Fully Close the Clip Arms</i> and <i>Lower the Gripper(s)</i> then repeat positioning and grasping steps.	27.1.4	Turn the <i>Arm Positioner</i> to <i>Neutral</i> .
24.6.2		If the Sleeve limits DC travel during grasping, an inadequate grasp may require repositioning of the MitraClip™ G4 System.	27.2	Deployment Step 2: Delivery Catheter Shaft Detachment
24.6.2.1		<i>Raise the Gripper(s)</i> and <i>Open the Clip Arms</i> to approximately 180 degrees and advance the DC handle. Repeat positioning and grasping steps as necessary (refer to Section 23.0 and 24.0).	27.2.1	Confirm that the Arm Positioner is Neutral. Remove the Release Pin from the DC Handle.
25.0	CLOSING THE CLIP AND EVALUATING CLIP POSITION		27.2.2	Turn the Arm Positioner in the “Open” direction until the Release Pin groove is fully exposed.
25.1		<i>Lock the Clip.</i>	NOTE:	After the Release Pin is removed, turning the Arm Positioner in the “Open” direction will not open the Clip Arms.
	WARNING:	Failure to Lock the Clip may result in loss of leaflet capture and insertion. Loss of leaflet capture and insertion may result in inadequate reduction of mitral regurgitation and may result in a single leaflet device attachment (SLDA).	27.2.3	Turn the Actuator Knob of the DC approximately 8 turns in the direction of the arrow printed on the Actuator Knob.
25.2		Slowly close the Clip just until the leaflets are coapted and MR is sufficiently reduced. The Clip should maintain a distinct “V” shape.		If it is difficult to turn the Actuator Knob, STOP and confirm that the Arm Positioner has been turned in the “Open” direction, such that the Release Pin groove is fully exposed.
	WARNING:	DO NOT use excessive force to close the Clip further than is necessary to adequately reduce MR. Leaflet injury may occur. DO NOT close the Clip too tightly as it may result in leaflet injury or an inability to deploy the Clip. Inability to deploy the Clip may result in worsening mitral regurgitation, cardiac injury, a single leaflet device attachment (SLDA), and / or conversion to surgical intervention.	WARNING:	Stop turning the Actuator Knob when resistance is felt, otherwise it may result in inability to deploy the Clip. Inability to deploy the Clip may result in worsening mitral regurgitation, cardiac injury, a single leaflet device attachment (SLDA), and / or conversion to surgical intervention.
	WARNING:	Failure to turn the Arm Positioner at least ½ turn in the “Close” direction after locking the Clip may result in loss of leaflet capture and insertion. Loss of leaflet capture and insertion may result in inadequate reduction of mitral regurgitation and may result in a single leaflet device attachment (SLDA).	27.2.4	Retract the Actuator Knob approximately 0.5 cm after it is fully unthreaded.
25.3		Use echocardiographic imaging to verify valve function, satisfactory coaptation, and insertion of both leaflets by observation of:	27.2.5	Fully retract the Gripper Levers.
		<ul style="list-style-type: none"> • Leaflet immobilization • Single or multiple valve orifice(s) • Limited leaflet mobility relative to the tips of both Clip Arms • Adequate MR reduction 	WARNING:	Do retract the Gripper Levers fully prior to retracting the DC Handle. Failure to retract the Gripper Levers may result in higher forces to deploy the clip. This may result in worsening mitral regurgitation, cardiac injury or a single leaflet device detachment (SLDA).
25.3.1		If the Clip position is not satisfactory, <i>Raise the Gripper(s)</i> , <i>Unlock the Clip</i> and <i>Invert the Clip Arms</i> .	27.2.6	Release the DC Fastener, and slowly retract the DC Handle until the DC Radiopaque Ring is against the tip of the Sleeve.
			27.2.6.1	If resistance is felt during DC Detachment and Clip separation from the DC can be confirmed by fluoroscopy, confirm the Gripper Levers are fully retracted. If resistance is still felt, access the Gripper Lines.