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Rev B
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EC REP
Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

CH REP
MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

UK REP
Emergo Consulting Limited
c/o C/MED/LA Innovation
Compass House, Vision Park
Histon, Cambridge
CB24 9BZ

Thompson Retractor

EN | ENGLISH
INFO SHEET INSTRUCTIONS FOR USE OF THE THOMPSON EMITTER HOLDER SYSTEM FOR MEDTRONIC™

BAHASA MELAYU
ARAHAN UNTUK PENGGUNAAN SISTEM PEMEGANG PEMANCAR THOMPSON UNTUK MEDTRONIC™

DA | DANSK
VEJLEDNING TIL BRUGSANVISNINGER TIL THOMPSON EMITTERHOLDERSYSTEM TIL MEDTRONIC™

DE | DEUTSCH
MERKBLATT MIT ANWEISUNGEN ZUR VERWENDUNG DES THOMPSON EMITTER-HALTERUNGSSYSTEMS FÜR MEDTRONIC™

ES | ESPAÑOL
INSTRUCCIONES DE USO DEL SISTEMA DE SOPORTE DEL EMISOR THOMPSON PARA MEDTRONIC™

ET | EESTI KEEL
JUHISED THOMPSON EMITTERHOLDERSYSTEM KASUTAMISEKS MEDTRONIC™

FI | SUOMI
OHJEET THOMPSON EMITTERHOLDER -JÄRJESTELMÄN KÄYTTÖÖN MEDTRONIC™:LLE

FR | FRANÇAIS
FICHE D'INFORMATIONS RELATIVE AUX INSTRUCTIONS D'UTILISATION DU SYSTÈME DE SUPPORT D'ÉMETTEUR THOMPSON POUR MEDTRONIC™

EL | ΕΛΛΗΝΙΚΑ
ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ ΓΙΑ ΤΟ ΣΥΣΤΗΜΑ ΣΤΗΡΙΞΗΣ ΕΚΠΟΜΠΟΥ THOMPSON ΓΙΑ MEDTRONIC™

HU | MAGYAR
A Medtronic™ készülékhez gyártott Thompson sugárzóvivő-tartó rendszer használati útmutatója

IS | ÍSLENSKA
Thompson geislahaldarakerfisleiðbeiningar fyrir Medtronic™

IT | ITALIANO
Sistema del supporto per emettitore Thompson per Medtronic™

JA | 日本語
Medtronic™ 用 Thompson エミッターホルダーシステムの取扱説明書

KO | 한국어
Medtronic™용 Thompson 이미터 홀더 시스템 사용 설명서

LT | LIETUVIŲ
„Thompson“ siųstuvo laikiklio sistemos, skirtos „Medtronic™“, naudojimo instrukcijų informacinis lapas

LV | LATVIEŠU
Informatīvā lapa par lietošanas norādījumiem Thompson emitētāja turētāja sistēmai Medtronic™

NL | NEDERLANDS
INFOBLAD MET GEBRUIKSAANWIJZINGEN VOOR HET THOMPSON EMITTERHOUDERSYSTEEM VOOR MEDTRONIC™

NO | NORSK
INFORMASJONSARK MED BRUKSANVISNINGER FOR THOMPSON EMITTERHOLDERSYSTEM FOR MEDTRONIC™

PL | POLSKI
INSTRUKCJE DOTYCZĄCE KORZYSTANIA Z SYSTEMU UCHWYTU EMITERA THOMPSON DLA MEDTRONIC™

PT | PORTUGUÊS
INSTRUÇÕES DE UTILIZAÇÃO DO SISTEMA DE SUPORTE DE EMISSOR THOMPSON PARA A MEDTRONIC™

RO | ROMÂNĂ
INSTRUCȚIUNI IMPORTANTE PARA UTILIZAREA SISTEMULUI DE SUPORT DE EMITOR THOMPSON PENTRU MEDTRONIC™

SV | SVENSKA
INFORMATIONSBLAD MED BRUKSANVISNINGAR FÖR SYSTEMET FÖR EMITTERHÅLLARE FRÅN THOMPSON FÖR MEDTRONIC™

TR | TÜRKÇE
MEDTRONIC™ İÇİN THOMPSON EMİTTER TUTUCU SİSTEMİNİN KULLANIMINA İLİŞKİN ÖNEMLİ TALİMAT

ZH-HANS | 简体中文
MEDTRONIC™ 的 THOMPSON EMITTER 托架系统使用说明书

ZH-HANT | 繁體中文
MEDTRONIC™ 的 THOMPSON EMITTER 支架系統使用說明書

SYMBOL LEGEND:

Manufacturer	Country of Manufacture	Date of Manufacture	Batch Code
3082	6249	2412	2492
Производител	Страна на производ.	Дата на производство	Код на партида
Výrobce	Země výroby	Datum výroby	Dávkové číslo
Producent	Fremstillingsland	Fremstillingsdato	Batchkode
Hersteller	Herstellungsland	Herstellungsdatum	Chargencode
Κατασκευαστής	Χώρα κατασκευής	Ημερομηνίας κατασκευής	Ενδεικτικός αριθμός
Fabricante	País del fabricante	Fecha de fabricación	Código de lote
Tootja	Tootja riik	Tootmiskuupäev	Partikkood
Valmistaja	Valmistusmaa	Valmistuspäivämäärä	Maahantuoja
Fabricant	Pays de fabrication	Date de fabrication	Code de lot
Proizvođač	Zemlja proizvodnje	Datum proizvodnje	Kôd serije
Gyártó	A gyártás országa	A gyártás dátuma	Importőr
Producent	Kraj produkcji	Data produkcji	Kod serii
Framleiðandi	Land framleiðanda	Framleiðsludagsetning	Lotukóði
Fabricante	Paese di produzione	Data di fabbricazione	Numero di lotto
Φορέας/χειριστής	Φορέας/χειριστής κινητ.	κ/κατηρητικών	Παρτίδα κωδ.
Gamintojas	Pagamintmo šalis	Pagaminimo data	Partijos kodas
Ražotājs	Ražošanas valsts	Izgatavošanas datums	Partijas kods
Производител	Земја на производство	Датум на производство	Број на серија
Manufatur	Pajjiż tal-Manifattura	Data tal-Manifattura	Importatur
Fabrikant	Land van fabricage	Fabricagedatum	Importeur
Producent	Kraj produkcji	Data produkcji	Importer
Fabricante	País de fabrico	Data de fabrico	Importador
Fabricante	País de fabricação	Data de fabricação	Importador
Producător	Țara de fabricație	Data fabricației	Importator
Производитель	Страна производства	Дата производства	Импортер
Výrobca	Krajina výroby	Dátum výroby	Kód šarže
Proizvajalec	Država proizvodnje	Datum proizvodnje	Oznaka serije
proizvođač	zemlja proizvodnje	datum proizvodnje	oznaka serije
Tillverkare	Tillverkningsland	Tillverkningsdatum	Batchkod
Üretici	Üretildiği Ülke	Üretim Tarihi	Parti Kodu
Виробник	Країна виробництва	Дата виготовлення	Код партії

REF			
Catalog Number	Do Not Reuse	Non-Sterile	Caution
2493	1050	2609	0434A
Каталожен номер	Да не се използва повторно	Нестерилно	Внимание
Katalogové číslo	Nepoužívejte opakovaně	Nesterilní	Upozornění
Katalognummer	Må ikke genbruges	Usteril	Forsigtig
Katalognummer	Ikke til genbrug	Usterilt	Forsiktig
Catalogusnummer	Niet hergebruiken	Niet-steriel	Let op
Katalognummer	Skal ikke gjenbrukes	Ikke-steril	Forsiktig
Numer katalogowy	Nie używać ponownie	Niesterylny	Przestroga
Número de catálogo	Não reutilizar	Não estéril	Precaução
Número de catálogo	Não reutilizar	Não estéril	Cuidado
Număr de catalog	Nu reutilizați	Nesteril	Atenție
Номер по каталогу	Повторное использование запрещено	Нестерильно	Внимание!
Katalógové číslo	Nepoužívajte opakovane	Nesterilné	Upozornenie
Kataloška številka	Ne uporabite ponovno	Nesterilno	Pozor
kataloški broj	nemojte ponovno koristiti	nesterilno	oprez
Katalognummer	Får ej återanvändas	Icke-steril	Försiktighetsåtgärd
Katalog Numarası	Tekrar Kullanmayın	Steril Değildir	Dikkat
Номер за каталогом	Не використовувати повторно	Нестерильна	Застереження

Rx Only	MD	UDI	
Translation	CAUTION: Federal law (USA) restricts these products to sale by or on the order of a physician	Medical Device	Unique Device Identifier
Превод	ВНИМАНИЕ: Федералният закон (САЩ) ограничава продажбата на тези устройства да се извършва само от лекар или по негово предписание	Медицинско устройство	Уникален идентификатор на устройството
Překlad	UPOZORNĚNÍ: Podle federálních zákonů USA smí být tento prostředek prodáván pouze lékařem nebo na lékařský předpis	Zdravotnická pomůcka	Jedinečný identifikátor prostředku
Oversættelse	FORSIGTIG: Ifølge amerikansk lovgivning må disse produkter kun sælges af en læge eller efter ordre fra en læge	Medicinsk udstyr	Unik udstyrs-id
Übersetzung	VORSICHT: In den USA dürfen diese Produkte nach den gesetzlichen Bestimmungen nur durch einen Arzt oder auf ärztliche Verordnung verkauft werden	Medizinprodukt	Unique Device Identifier
Μετάφραση	ΠΡΟΣΟΧΗ: Η ομοσπονδιακή νομοθεσία των Ηνωμένων Πολιτειών (ΗΠΑ) περιορίζει τη χορήγηση αυτών των προϊόντων στον ιατρό ή κατόπιν εντολής ιατρού	Ιατροτεχνολογικό προϊόν	Αποκλειστικό αναγνωριστικό προϊόντος
Tradução	AVISO: a legislação federal dos EUA restringe a venda destes produtos a médicos ou por prescrição médica	Produto sanitário	Identificador único do dispositivo
Traducción	ATENCIÓN: Las leyes federales americanas restringen la venta de estos productos a médicos o por prescripción facultativa	Producto sanitario	Identificador único del dispositivo
Tõlge	ETTEVAATUST! Föderaalseadus piirab nende toodete müüki ainult arstidele või korraldab müügi	Meditsiiniseade	Seadme kordumatu identifitseerimismärgis
Käännös	HUOMIO: Yhdysvaltojen liittovaltion laki rajoittaa tuotteiden myynnin lääkäreille tai määräyksellä	Lääkinnällinen laite	Yksilöllinen tuotetunniste
Traduction	MISE EN GARDE : La législation fédérale américaine limite la vente de ces produits devant être vendus à un médecin ou sur ordonnance médicale	Dispositif médical	Identifiant unique du dispositif
Prijevod	OPREZ: Savezni zakon (SAD) ograničava prodaju ovih proizvoda isključivo liječnicima ili po nalogu liječnika	Medicinski uređaj	Jedinstveni identifikator uređaja
Fordítás	FIGYELEM: A szövetségi jogszabályok (USA) értelmében ezek csak orvos által vagy orvosi rendelvényben vásárolhatók	Orvostechnikai eszköz	Egyedi eszközazonosító
Terjemahan	PERHATIAN: Hukum Federal (AS) membatasi penjualan produk ini untuk dijual oleh atau atas permah dokter	Perangkat Medis	Pengidentifikasi Perangkat Unik
Þýðing	VARÚÐ: Alríkislög (Bandaríkin) takmarka sölu þessara vara við lækna eða samkvæmt fyrirmælum lækna	Lækningatæki	Einkvæm tækjaauðkenning
Traduzione	ATTENZIONE: La legge federale statunitense limita la vendita di questi prodotti ai medici o dietro prescrizione medica	Dispositivo medico	Identificativo univoco del dispositivo
Vertimas	DĖMESIO: Pagal federalinius JAV įstatymus šiuos gaminius galima parduoti tik gydytojams arba jų įgaliotiesiems asmenims	Medicinos prietaisas	Unikalus prietaiso identifikatorius
Tulkojums	UZMANĪBU! Saskaņā ar ASV federālajiem likumiem šīs ierīces drīkst iekārtu vai pēc ārsta rīkojuma	Medicīniskā ierīce	Ierīces unikālais identifikators

Authorized representative in the European Union	CE Marking	Application Identifier for Global Trade Item Number (GTIN) per GS1 Specification	Application Identifier for Lot Number per GS1 Specification
Упълномощен представител в Европейския съюз	Маркировка CE	Идентификатор на приложението за глобален търговски номер на артикула съгласно спецификацията на GS1	Идентификатор на приложението за партиден номер съгласно спецификацията на GS1
Zplnomocněný zástupce ve Evropském společenství	Označení CE	Identifikátor aplikace pro globální obchodní číslo položky (GTIN) podle specifikace GS1	Identifikátor aplikace pro číslo šarže podle specifikace GS1
Autoriseret repræsentant i Det Europæiske Fællesskab	CE-mærkning	Anvendelsesidentifikator for Global Trade Item Number (GTIN) i henhold til GS1-specifikation	Anvendelsesidentifikator for Varegruppenummer (Batch) i henhold til GS1-specifikation
Volmacht voor de Europese Unie	CE-markering	Toepassingsidentificatie voor Global Trade Item Number (GTIN) volgens de GS1-specificaties	Toepassingsidentificatie voor partijnummer per GS1-specificaties
Volitud esindaja Euroopa Liidus	CE-märgis	Globaalse kaubanimeti kaupade tuvastusidentifikaatori (GTIN) rakendusidentifikaator GS1 spetsifikatsiooni järgi	Partiinumbri rakendusidentifikaator GS1 spetsifikatsiooni järgi
Valtuutettu edustaja Euroopan unionissa	CE-merkintä	Global Trade Item Number (GTIN) -tuotetunnuksen sovellutusnumero GS1-sovellutusmäärityksen mukaisesti	Erän numeron sovellutusnumero GS1-sovellutusmäärityksen mukaisesti
Représentant agréé en Suisse	CE-marquage	Identifiant d'application pour le numéro d'article commercial mondial (GTIN) selon la spécification GS1	Identifiant d'application pour le numéro de lot selon la spécification GS1
Ovlašteni predstavnik u Švicarskoj	CE-oznaka	Identifikator primjene za globalni broj trgovačke jedinice (GTIN) prema specifikaciji GS1	Identifikator primjene za broj serije prema specifikaciji GS1
Svájci képviselet	CE-jelölés	A globális kereskedelmi tételszám (GTIN) alkalmazásazonosítója a GS1-előírás szerint	Gyártási tételszám alkalmazásazonosítója a GS1-előírás szerint
Svizzera rappresentante autorizzato	Marcatura CE	Identificativo applicazione per il numero di articolo commerciale globale (Global Trade Item Number, GTIN) secondo le specifiche GS1	Identificativo applicazione per il numero di lotto secondo le specifiche GS1
Įgaliotasis atstovas Šveicarijoje	CE ženklinimas	Taikomųjų programų identifikatorius, skirtas pasaulinio prekybos vieneto numeriui (GTIN) pagal GS1 specifikaciją	Taikomųjų programų identifikatorius, skirtas partijos numeriui pagal GS1 specifikaciją
Pilnvarotais pārstāvis Eiropas Savienībā	CE zīme	Globālā tirdus vienības numura (GTIN) lietojumprogrammas identifikators saskaņā ar GS1 specifikāciju	Partijas numura lietojumprogrammas identifikators saskaņā ar GS1 specifikāciju
Овластен претставник во Швајцарија	Ознака CE	Идентификатор на апликација за глобален број на трговска единица (GTIN) според спецификација на GS1	Идентификатор на апликација за број на серија според спецификација на GS1
Awtorizzat rappreżentant fl-Ewropa	Marka CE	Identifikatur tal-applikazzjoni għan-Numru Globali tal-Oġġett Kummerċjali (GTIN) skont l-ispeċifikazzjoni GS1	Identifikatur tal-applikazzjoni għan-Numru tal-Lott skont l-ispeċifikazzjoni GS1
Gemachtigde nell'Unione europea	Marcatura CE	Identificatore di applicazione per il numero mondiale di articolo commerciale (GTIN) secondo le specifiche GS1	Identificatore di applicazione per il numero di lotto secondo le specifiche GS1
Mandatario nell'Unione europea	Marcatura CE	Identificatore di applicazione per il numero mondiale di articolo commerciale (GTIN) secondo le specifiche GS1	Identificatore di applicazione per il numero di lotto secondo le specifiche GS1
Europarlament, Ogólnoeuropejski uprawniony agent	CE-oznakowanie	Identyfikator zastosowania dla globalnego numeru jednostki handlowej (GTIN) zgodnie ze specyfikacją GS1	Identyfikator zastosowania dla numeru partii zgodnie ze specyfikacją GS1
Representante autorizado na Suíça	Marcação CE	Identificador de aplicação para o número global de artigo comercial (GTIN) de acordo com a especificação GS1	Identificador de aplicação para o número de lote de acordo com a especificação GS1
Reprezentant autorizat în Elveția	Marcajul CE	Identificatorul aplicației pentru numărul global comercial de articol (GTIN) conform specificației GS1	Identificatorul aplicației pentru numărul lotului conform specificației GS1
Уполномоченный представитель в Швейцарии	Маркировка CE	Идентификатор применения для глобального идентификационного номера единицы торговли (GTIN) согласно спецификации GS1	Идентификатор применения для номера партии согласно спецификации GS1
Splnomocnený zástupca vo Švajčiarsku	Označenie CE	Identifikátor aplikácie pre globálne obchodné číslo položky (GTIN) podľa špecifikácie GS1	Identifikátor aplikácie pre číslo šarže podľa špecifikácie GS1
Pooblaščeni predstavnik v Švici	oznaka CE	Identifikator uporabe za globalno trgovsko številko (GTIN) v skladu s specifikacijo GS1	Identifikator uporabe za številko serije v skladu s specifikacijo GS1
Auktoriserad representant i Europeiska unionen	CE-märkning	Applikationsidentifierare för global handelsvaruidentifikation (GTIN) enligt GS1-specifikationen	Applikationsidentifierare för tillverkarens batchnummer enligt GS1-specifikationen
Yetkili temsilci	CE İşareti	GS1 Spesifikasyonu uyarınca Küresel Ticari Ürün Numarası (GTIN) için Uygulama Tanımlayıcısı	GS1 Spesifikasyonu uyarınca Parti Numarası için Uygulama Tanımlayıcısı
Уповноважений представник у Європейському Союзі	Маркування CE	Ідентифікатор програми для глобального номера торгової одиниці (GTIN) відповідно до специфікації GS1	Ідентифікатор програми для номера партії відповідно до специфікації GS1

SYMBOLS LEGEND (continued):

CH REP	UK REP	UKCA	kg
Authorised representative in Switzerland	Authorised representative in the United Kingdom	UKCA Marking	Mass of Mounted Part
Упълномощен представител в Швейцария	Упълномощен представител в Обединеното кралство	Маркировка UKCA	Маса на монтираната част
Zplnomocněný zástupce ve Švýcarsku	Zplnomocněný zástupce ve Spojeném království	Označení UKCA	Hmotnost namontovaného dílu
Autoriseret repræsentant i Schweiz	Autoriseret repræsentant i Storbritannien	UKCA-mærkning	Masse af monteret del
Autorisierter Vertreter in der Schweiz	Autorisierter Vertreter im Vereinigten Königreich	UKCA-Kennzeichnung	Masse des montierten Teils
Εξουσιοδοτημένος αντιπρόσωπος στη Ελβετία	Εξουσιοδοτημένος αντιπρόσωπος στο Ηνωμένο Βασίλειο	Σήμανση UKCA	Μάζα τοποθετημένου εξαρτήματος
Representante autorizado en Suiza	Representante autorizado en el Reino Unido	Marcado UKCA	Masa de la pieza montada
Volitatud esindaja Šveitsis	Volitatud esindaja Ühendkuningriigis	UKCA märgistus	Paigaldatud osa mass
Valtuutettu edustaja Sveitsissä	Valtuutettu edustaja Yhdistyneessä kuningaskunnassa	UKCA-merkintä	Kiinnitetyn osan massa
Representant agréé en Suisse	Représentant autorisé au Royaume-Uni	Marquage UKCA	Masse de la pièce montée
Ovlašćeni predstavnik u Švajcarskoj	Ovlašćeni predstavnik u Ujedinjenom Kraljevstvu	Oznaka UKCA	Masa montiranog dijela
Meghatalmazott képviselő Svájcban	Meghatalmazott képviselő az Egyesült Királyságban	UKCA-jelölés	Rezsnél felszerelt alkatrész tömege
Perwakilan resmi di Swiss	Perwakilan resmi di Britania Raya	Tanda UKCA	Massa Bagian yang Terpasang
Várukerendész fultrúi i bPasfort	Várukerendész fultrúi i dTeritéar Aontaithe	UKCA marking	Maisú uispeirts thiar
Mandatario in Svizzera	Mandatario nel Regno Unito	Marcatura UKCA	Massa della parte montata
Uzņēmējsabiedrība Šveicē pārstāvēšanai	Kuzavca Karoņuzņēmēji pārstāvēšanai	UKCA Ženklinimas	Montuojamo dalies masė
Įgaliotasis atstovas Šveicarijoje	Įgaliotasis atstovas Jungtinėje Karalystėje	UKCA žymėjimas	Montuojamos dalies masė
Pārvaldes pārstāvis Šveicē	Pārvaldes pārstāvis Apvienotajā Karalistē	UKCA marķējums	Uzstādāmās daļas masa
Овластен претставник во Швајцарија	Овластен претставник во Обединетото Кралство	Ознака UKCA	Маса на монтиран дел
Reġistrant awtorizzat fl-Isvizzera	Rappreżentant awtorizzat fir-Renju Unit	Markatura UKCA	Massa tal-parti Mwaħħla
Gevolmachtigde vertegenwoordiger in het Verenigd Koninkrijk	Gevolmachtigde vertegenwoordiger in Zwitserland	UKCA-markering	Massa van gemonteerd onderdeel
Autoriseret repræsentant i Storbritannien	Autoriseret repræsentant i Schweiz	UKCA-mærkning	Masse til montert del
Upprunaland	Upprunaland	Ursprungsland	Ursprungsland
Швајцарија	Обединето Кралство	Маркирана UKCA	Маса монтирачки части
Autorizovaný zástupca vo Švajčiarsku	Autorizovaný zástupca spojeného kráľovstva	Označenie UKCA	Hmotnosť namontovanej časti
Pooblaščeni zastopnik v Švici	Pooblaščeni zastopnik v Združenem kraljestvu	Oznaka UKCA	Masa nameščenega dela
ovlašćeni predstavnik u Švajcarskoj	ovlašćeni predstavnik u Ujedinjenom Kraljevstvu	oznaka UKCA	masa montiranog dela
Auktoriserad representant i Schweiz	Auktoriserad representant i Storbritannien	UKCA-märkning	Monterad delsmassa
Ivoire de yetkili temsilci	Birleşik Krallık'ta yetkili temsilci	UKCA İşareti	Montaj Parçasının Kütlesi
Уповноважений представник у Швейцарії	Уповноважений представник у Великій Британії	Маркування UKCA	Маса змонтованої частини

EN | ENGLISH

Thompson Emitter Holder System for Medtronic™, Manufactured by Thompson Surgical Instruments, Inc.

IMPORTANT INSTRUCTIONS FOR USE OF THE THOMPSON EMITTER HOLDER SYSTEM FOR MEDTRONIC™
PLEASE READ BEFORE USE

The Thompson Emitter Holder System can be safely used when care personnel is safe use and handling practices, effective reprocessing, and maintenance of the Thompson Emitter Holder System for Medtronic™. Failure to follow these instructions could result in improper function of the device and injury to the patient and/or user.

The use of three guidelines does not remove or limit the user's ultimate responsibility for cleanliness and sterility of any Thompson Surgical instruments. Thompson Surgical Instruments, Inc. has provided these guidelines based upon information that we believe is reliable. However, we do not guarantee the results as we cannot monitor or control the actual use of our instruments.

⚠ The Thompson Emitter Holder System for Medtronic™ is not intended to treat or monitor any disease conditions. Failure to follow these instructions could result in improper function of the device and injury to the patient and/or user and warranty or service agreement.

DEVICE DESCRIPTION

The Thompson Emitter Holder System for Medtronic™ is a reusable device designed to provide a stable platform for holding an Electromagnetic Emitter to a surgical operating table rail. The Thompson Emitter Holder System for Medtronic™ is designed to be used with the Medtronic™ Electromagnetic Emitter and Stealth Station™ S7™ System.

⚠ The Thompson Surgical Emitter Holder System for Medtronic™ is designed to be used with the Medtronic™ Electromagnetic Emitter and Stealth Station™ S7™ System. Use with other systems may result in improper function of the device and injury to the patient and/or user.

INTENDED USE

The Thompson Emitter Holder System is intended to provide a stable platform for holding an Electromagnetic Emitter to a surgical operating table rail. The Thompson Emitter Holder System for Medtronic™ is designed to be used with the Medtronic™ Electromagnetic Emitter and Stealth Station™ S7™ System.

⚠ The Thompson Surgical Emitter Holder System for Medtronic™ is designed to be used with the Medtronic™ Electromagnetic Emitter and Stealth Station™ S7™ System. Use with other systems may result in improper function of the device and injury to the patient and/or user.

CONTRAINDICATIONS

None known.

⚠ **WARNINGS, PRECAUTIONS, RESIDUAL RISKS, AND UNDESIRABLE SIDE EFFECTS**

- Thompson Surgical Instruments, Inc. is not responsible for any damage to the Thompson Emitter Holder System caused by improper literature and videos, including assembly, use, and disassembly, by persons who have not been trained in the proper use of the Thompson Emitter Holder System. Patient injury, including but not limited to, tissue, nerve, or vascular damage, may occur if the Thompson Emitter Holder System is not used in accordance with the Thompson Surgical Instruments, Inc. instructions for use.
- Many variables such as patient anatomy, pathology, and surgical technique may influence the procedure's outcome. Patient, product, and procedure selection are the responsibility of the surgeon. Thompson Surgical Instruments, Inc. does not practice medicine and does not recommend any particular procedure for use with a specific patient. The surgeon must rely on his or her professional clinical training and experience when selecting a particular procedure prescribed by a well-trained physician for use with a specific patient.
- Refer to your hospital's policies and procedures for infection control, handling, cleaning/decontamination, and disposal of used devices.
- Do not use if packaging is damaged.
- Only sterile, unopened non-sterile and must be cleaned, inspected, and sterilized prior to initial use and after each subsequent use to reduce the risk of patient or user infection.
- Normal equipment use has little effect on these instruments. Determine end of life by wear and damage due to use. Product should be inspected and functionally tested before each use. Do not use if damaged or worn. Damage may include, but is not limited to, cracks, chips, dents, scratches, or corrosion. Do not use if marking, alignment, or adjustment is difficult or unreliable. Do not use if the device does not function properly. Do not use if the device is missing components. Do not use if the device is bent or misaligned. Do not use if the device is loose or unstable and could result in unexpected movement of the emitter or introduction of unexpected stress which could result in patient or user injury.
- Do not use if the device is contaminated with unknown substances. Do not use if the device is contaminated with body fluids. Contaminated devices can cause infection or cross-contamination. Do not use if the device is contaminated with body fluids. Contaminated devices can cause infection or cross-contamination.
- CUIDADO: A ley federal (EEUU) restringe a venta destes aparelhos a médicos ou a pedido médico.
- Refer to your hospital's policies and procedures for infection control, handling, cleaning/decontamination, and disposal of used devices.
- Refer to the Thompson Surgical Instruments, Inc. website at www.thompsonsurgical.com for the latest version of the Instructions for Use.
- Refer to the Thompson Surgical Instruments, Inc. website at www.thompsonsurgical.com for what is described here and in associated user manuals, provided by Medtronic™ or Thompson Surgical Instruments, Inc. Do not use any instruments, systems, or software in any way that is described here or in associated user manuals, provided by Medtronic™ or Thompson Surgical Instruments, Inc., unless otherwise specified by the manufacturer.
- Ensure frame components, clamps, nut adapters, holders, and accessories are securely positioned and locked into place before use to avoid sudden movement or loosening during surgical procedure.
- Metal components are reusable and can be exposed to multiple cycles of cleaning and sterilization. Inspect and test prior to each use. Failure to correct for broken or loose components may result in patient injury.
- Do not use if the device has been dropped or physically impacted. Dropped or impacted devices may have latent damage that could result in patient injury.
- Do not use if the device has been exposed to unexpected heat or flame. Heat can cause damage to the device. Avoid exposure of your devices to excessive heat.

CLEANING

Adequate reprocessing is contingent upon the thoroughness of cleaning. To ensure acceptable reprocessing, do not delay between the steps below. Before cleaning, remove all visible soil. Use only the cleaning methods listed below. Thompson Surgical Instruments, Inc. has validated the following cleaning methods. Any other cleaning method must be validated by the user.

Automated cleaning is preferred for automated and manual cleaning for instruments and accessories.

Cleaning/rinsing agents are validated for use with:

Point of Use (Optional):
- Remove all visible soil from instruments using non-shedding wipes.
- Wipes moistened with 70% (v/v) isopropyl alcohol or other cleaning instruments should be cleaned within 30 minutes of use to minimize drying. Do not immerse instruments in isopropyl alcohol.

Manual Cleaning:
- **Prior to the first use of all instruments with lumens, Manual cleaning NOT ALLOWED for the Articulating Arms. See automated cleaning below.**
- Thoroughly clean all instruments with lumens immediately after use. Flush lumens with a minimum of 10 ml of water. Use a brush if necessary. Use a syringe if water is recommended. Do not exceed water should be used for the final rinse step to prevent mineral deposits on surfaces. The following cleaning agents, equipment, and parameters have been validated for manual cleaning of instruments with lumens. Any other cleaning method must be validated by the user.
- Prepare an enzymatic cleaning solution using Neodisher® MediClean forte with a concentration of 0.5% (5 ml/1000 ml) and warm water (≤ 35 °C/95 °F).
- Soak instruments with lumens in the enzymatic cleaning solution for at least 5 minutes.
- Rinse and flush instruments under running tap water for 3 minutes.
- Prepare an alkaline cleaner solution using Neodisher® MediClean forte with a concentration of 0.5% (5 ml/1000 ml) and warm water (≤ 35 °C/95 °F).
- Clean instruments with lumens with a brush, cleaner, compressed air, and suction for 10 minutes.
- Rinse instruments in the enzymatic cleaner, completely submerged, and suck for 10 - 60 seconds.
- Rinse and flush instruments under running tap water for 3 minutes. Use a brush, cleaner, compressed air, and suction or cavities in the water stream. Rinse for 3 minutes.
- Dry with a soft, lint-free cloth or filtered compressed air.
- Place the parts in the enzymatic cleaner, completely submerged, and suction for 10 - 60 seconds.
- Rinse and flush instruments under running tap water for 3 minutes. Use a brush, cleaner, compressed air, and suction or cavities in the water stream. Rinse for 3 minutes.
- Dispose rinse water after each use.
- Inspect instruments, including lumens and cavities, to ensure contamination has been removed. If not, repeat the cleaning process. Do not proceed with reprocessing if contamination is still present.

Validated Manual Cleaning Parameters:

PHASE	TIME (MIN.)	TEMP.	DETERGENT/ CONCENTRATION
Pre-soak	5	Cold Tap Water	N/A
Enzyme Wash	5	Hot Tap Water	(1 – 2 ml/gal)
Neutral pH Detergent Wash	10	43°C (110°F)	(1 – 2 ml/gal)
Rinse 1	3	Hot Tap Water	N/A
Purified Water Rinse	3	82°C (180°F) minimum	N/A
Drying	10	115°C (240°F)	N/A

Note: Enzymatic cleaning cycle validated using Enzol® enzymatic detergent. Neutral pH detergent validated using Prolystica® 2X Concentrate Neutral Detergent. Ultrasonic cleaning validated using Crest® Ultrasonic Cleaning Solution. Cleaning validated using Miele® PG 8583 washer disinfector. Consult detergent manufacturer's recommendations. The automated cleaning cycle was validated using a Miele® PG 8583 washer, fully assembled, operated to maximize surface exposure.

Automated Enzymatic Cleaning Parameters:

PHASE	TIME (MIN.)	TEMP.	DETERGENT/ CONCENTRATION
Pre-wash	2:00	Cold Tap Water	N/A
Enzyme Wash	5:00	Hot Tap Water	(1 – 2 ml/gal)
Rinse 1	2:00	Hot Tap Water	N/A
Rinse 2	2:00	82°C (180°F) minimum	N/A
Drying	10:00	115°C (240°F)	N/A

Note: Enzymatic cleaning cycle validated using Enzol® enzymatic detergent. Ultrasonic cleaning validated using Crest® Ultrasonic Cleaning Solution. Cleaning validated using Miele® PG 8583 washer disinfector. Consult detergent manufacturer's recommendations. The automated cleaning cycle was validated using a Miele® PG 8583 washer, fully assembled, operated to maximize surface exposure.

Point of Use (Optional):
- Remove all visible soil from instruments using non-shedding wipes.
- Wipes moistened with 70% (v/v) isopropyl alcohol or other cleaning instruments should be cleaned within 30 minutes of use to minimize drying. Do not immerse instruments in isopropyl alcohol.

Manual Cleaning:
- **Prior to the first use of all instruments with lumens, Manual cleaning NOT ALLOWED for the Articulating Arms. See automated cleaning below.**
- Thoroughly clean all instruments with lumens immediately after use. Flush lumens with a minimum of 10 ml of water. Use a brush if necessary. Use a syringe if water is recommended. Do not exceed water should be used for the final rinse step to prevent mineral deposits on surfaces. The following cleaning agents, equipment, and parameters have been validated for manual cleaning of instruments with lumens. Any other cleaning method must be validated by the user.
- Prepare an enzymatic cleaning solution using Neodisher® MediClean forte with a concentration of 0.5% (5 ml/1000 ml) and warm water (≤ 35 °C/95 °F).
- Soak instruments with lumens in the enzymatic cleaning solution for at least 5 minutes.
- Rinse and flush instruments under running tap water for 3 minutes.
- Prepare an alkaline cleaner solution using Neodisher® MediClean forte with a concentration of 0.5% (5 ml/1000 ml) and warm water (≤ 35 °C/95 °F).
- Clean instruments with lumens with a brush, cleaner, compressed air, and suction for 10 minutes.
- Rinse instruments in the enzymatic cleaner, completely submerged, and suck for 10 - 60 seconds.
- Rinse and flush instruments under running tap water for 3 minutes. Use a brush, cleaner, compressed air, and suction or cavities in the water stream. Rinse for 3 minutes.
- Dry with a soft, lint-free cloth or filtered compressed air.
- Place the parts in the enzymatic cleaner, completely submerged, and suction for 10 - 60 seconds.
- Rinse and flush instruments under running tap water for 3 minutes. Use a brush, cleaner, compressed air, and suction or cavities in the water stream. Rinse for 3 minutes.
- Dispose rinse water after each use.
- Inspect instruments, including lumens and cavities, to ensure contamination has been removed. If not, repeat the cleaning process. Do not proceed with reprocessing if contamination is still present.

Validated Manual Cleaning Parameters:

PHASE	TIME (MIN.)	TEMP.	DETERGENT/ CONCENTRATION
Pre-soak	5	Cold Tap Water	N/A
Enzyme Wash	5	Hot Tap Water	(1 – 2 ml/gal)
Rinse 1	3	Hot Tap Water	N/A
Purified Water Rinse	3	82°C (180°F) minimum	N/A
Drying	10	115°C (240°F)	N/A

Automated Enzymatic Cleaning Parameters:

PHASE	TIME (MIN.)	TEMP.	DETERGENT/ CONCENTRATION
Pre-wash	2:00	Cold Tap Water	N/A
Enzyme Wash	5:00	Hot Tap Water	(1 – 2 ml/gal)
Rinse 1	2:00	Hot Tap Water	N/A
Rinse 2	2:00	82°C (180°F) minimum	N/A
Drying	10:00	115°C (240°F)	N/A

Automated alkaline cleaning:

PHASE	TIME (MIN.)	TEMP.	DETERGENT/ CONCENTRATION
Pre-wash	2:00	Cold Tap Water	N/A
Alkaline wash	10:00	Hot Tap Water	(1 – 2 ml/gal)
Rinse 1	2:00	Hot Tap Water	N/A
Rinse 2	2:00	82°C (180°F) minimum	N/A
Drying	10:00	115°C (240°F)	N/A

*Alkaline detergent validated for use with Neodisher® MediClean forte. Consult detergent manufacturer's recommendations. The automated cleaning cycle was validated using a Miele® PG 8583 washer, fully assembled, operated to maximize surface exposure.

Automated alkaline soaking:

| PHASE | TIME

* detergenti alcalini con pH ≤12 possono essere usati per pulire strumenti in acciaio inox e polimeri in gas Plasma in cui ciò è richiesto dalla legge o normativa locale. Detergenti alcalini non devono essere usati per pulire strumenti in leghe di alluminio. Il metodo deve essere convalidato a cura dell'utente per garantire la rimozione completa di residui e risultati accurati / detergenti alcalini dopo dispositivo, che possono altrimenti reagire con conseguenze indesiderate della forma.

** Il metodo deve essere convalidato a cura dell'utente per garantire la rimozione completa di residui e risultati accurati / Non usare candeggina a base di NaClO. Medisafe Extra non è necessario e può causare corrosione su alcuni strumenti. Non usare detergenti enzimatici a causa di residui.

DISINFEZIONE TERMICA

Questo ciclo è convalidato per l'uso con acqua di rubinetto. Se necessario, può essere utilizzata acqua demineralizzata.

FASE	TEMPO (MIN.)	TEMP.	VOLUME DI SOLUZIONE
Risciacquo	2 min	+65 °C (+149 °F) Acqua calda	1 litro
Impulso termico	10 cicli	Variabile	
Disinfezione	5 min	+90 °C (+194 °F)	
Raffreddamento	5 min	+65 °C (+149 °F)	
Essiccazione	30 min	+110 °C (+230 °F)	

SPIEGONE, MANUTENZIONE e TEST

Ispezionare visivamente ogni dispositivo dopo ogni ciclo. Controllare che non presentino danni. Ispezionare prima dell'uso verifica visiva e funzionale dell'integrità e del meccanismo del prodotto. Non utilizzare in presenza di danni visibili di qualsiasi natura. Limitare il numero di strumenti visibilmente danneggiati e considerarli come rifiuti ospedalieri.

- Ispezionare con cura tutte le articolazioni. Non usare alcuno strumento che appaia disregolato o rotto (incrinato, deformato, non funzionante o allentato).
- Ispezionare con cura tutti gli strumenti. Non usare alcuno strumento che appaia danneggi