Thompson Surgical Instruments, Inc.
10341 East Cherry Bend Road
Traverse City, Michigan, USA
tel: +1 231 922 0177
fax: +1 231 922 0174

EC REP
Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

CH REP
Emergo Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

UK REP
Compass Medical Services
c/o C-1060-3, Interchange
Compass House, Vision Park Histon
Cambridge

Rev E
072825
trnvdfu@vaulta.

Thompson Retractor for Medtronic®, Manufactured by Thompson Surgical Instruments, Inc.

IMPORTANT INSTRUCTIONS FOR USE OF THE THOMPSON RETRACTOR FOR MEDTRONIC®

PLEASE READ BEFORE USE

It is the responsibility of the health care personnel in safe use and handling practices, effective reprocessing, and maintenance of all Thompson Surgical Instruments, Inc. products. Thompson Surgical Instruments, Inc. recommends that personnel be properly trained, cleaned, and disinfected prior to each use.

Thompson Surgical Instruments does not remove or limit the user's ultimate responsibility for directions and identity of any Thompson Surgical Instruments, Inc. product. Thompson Surgical Instruments, Inc. is providing recommendations that have proven effective in clinical practice. It is the duty of the processor to comply with said instructions.

The Thompson Retractor is not intended to treat or monitor any disease conditions. Failure to follow these instructions may cause harm to the patient, may render devices unusable, and void warranty or service agreements.

DEVICE DESCRIPTION

The Thompson Retractor for Medtronic® is a reusable device designed to provide access and exposure for a variety of surgical procedures. The Thompson Retractor for Medtronic® is manufactured from stainless steel and is provided non-sterile. It is available in a variety of patient anatomical sizes and configurations.

INTENDED USE

The Thompson Retractor is for distracting in the Anterior Lumbar Systems. The Thompson Retractor for Medtronic® is intended for use during surgical procedures in order to provide access and exposure. The Thompson Retractor is intended for use by well-informed physicians in appropriate health care facilities.

The intended patient population may vary according to the surgical procedure being performed. The device is not restricted to any patient population. Contact Thompson Surgical or Importer for additional information regarding Device Classification.

NOTE: DO NOT USE WITH ANY OTHER MANUFACTURER'S SYSTEMS.

Thompson Surgical Instruments systems and accessories are supplied non-sterile.

Thompson Surgical Instruments, Inc. products are intended to be used by a single patient per procedure. Any implant, device, sterilize, transport, and store Thompson Surgical Instruments, Inc. products in accordance with the instructions furnished with each device. Any use of this device in a manner not specifically intended as their own to maintain sterility; they are intended to be used in conjunction with a legally marketed and/or investigational device.

CONTRAINDICATIONS:

None Known

WARNINGS, PRECAUTIONS, RESIDUAL RISKS, AND UNDESIRABLE SIDE EFFECTS:

- Thompson Surgical Instruments, Inc. products are intended to be used by a single patient per procedure. Any implant, device, sterilize, transport, and store Thompson Surgical Instruments, Inc. products in accordance with the instructions furnished with each device. Any use of this device in a manner not specifically intended as their own to maintain sterility; they are intended to be used in conjunction with a legally marketed and/or investigational device.
- 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. Surgeons must rely on their clinical training and experience when selecting a particular instrument to perform a specific procedure. Surgeons must also be aware of the limitations of each instrument before using it. Instruments not sensitive are not considered.
- Surgeons must rely on their clinical judgment to decide when such retraction as necessary to provide adequate exposure and access in order to reduce the risk of damage to the tissue during retraction.
- Relax the retractor periodically to ensure proper blood flow in order to reduce the risk of patient injury, including tissue necrosis.
- Surgeons must rely on their clinical judgment to decide when such retraction is necessary to prevent nerve damage. See the surgeon's manual for components to meet various patient anatomies.
- Do not use the retractor blades as a lever to pry the vertebrae and exudate the need to use free running EMG to monitor events such as retractor nerve compression during the procedure. Failure to use free running EMG may result in patient injury or death.
- Table mounted frame prevents most retractors from moving relative to patient movement. Use caution when moving patient while retractor is in use to avoid injury to the patient.
- Do not move, modify, or alter the retractor during surgery. Doing so may result in patient injury or device failure. Use only as intended for distraction. Pins can break under undue stress and may create sharps which may cause patient injury.
- Do not use the retractor if the ratchet teeth are worn or damaged. Worn or damaged ratchet teeth may unexpected sharps which could cause patient injury.
- Products are provided non sterile and must be pre-cleaned, cleaned, visually examined, and sterilized before each use to reduce the risk of patient or user infection or cross-contamination.
- Normal repeated use has little effect on these instruments. Determine end of life by wear and damage due to use. Product should be discarded when worn, damaged, or bent. Do not use damaged instruments. Damaged instruments may break during use, causing injury to the patient or surgeon. Do not use damaged if markings such as Part # or Lot # are illegible. Illegible markings may cause the wrong instruments could result in sudden loss of exposure or introduction of unexpected sharps which could result in patient or user injury.
- Do not use the retractor if the ratchet teeth are worn or damaged. Worn or damaged ratchet teeth may unexpected sharps which could cause patient injury.
- Do not mix metals. Contact between dissimilar metals can cause galvanic corrosion, leading to material degradation and release of debris to the frame moving such as screwed separating time or patient injury.
- Do not use with cements or bone substitutes. Use of these with Thompson Surgical Products as provided in risk to the Thompson Surgical with incompatible Thompson Surgical Products. Thompson Surgical Products are not designed for use with incompatible handles and blades and the identified by their gold plunger and nipples, respectively, as well as matching serrations. Swivel-Grip (SG) blades have gold nipples, with matching serrations on the handle. Fixed-Grip (FG) blades have silver plunger and nipples, with matching serrations on the handle. Use of the Thompson Retractor for Medtronic® may cause damage or failure of the device which could result in serious patient injury or death.
- Use of the Thompson Retractor for Medtronic® may cause damage or failure of the device which could result in serious patient injury or death.
- Thompson Surgical Instruments, Inc. products are provided non sterile and must be pre-cleaned, cleaned, visually examined and locked into place before use to avoid sudden loss of exposure and reduce risk of subsequent patient injury.
- Thompson Surgical Instruments, Inc. products are provided non sterile and must be sterilized prior to use. Failure to do so may cause infection.
- Surgeons must rely on their clinical judgment to decide when such retraction is necessary to prevent nerve damage. See the surgeon's manual for components to meet various patient anatomies.
- **Prion Diseases:** Ground or destroy instruments in contact or exposed to patients with prion diseases, or those suspected of prion diseases. Thompson Surgical does not warrant effectiveness of cleaning instructions following exposure to prion diseases. Consult your infection control officer.

CLEANING

Thorough cleaning is a contingent upon the thoroughness of cleaning. To ensure acceptable reprocessing, do not delay between the days before. Before cleaning, remove all gross contamination. Do not use abrasive cleaners. Do not use metal brushes. Do not use chlorides. Do NOT allow instruments to dry after use, prior to cleaning. Cleaning and sterilization may be hindered when blood or bloody solutions are allowed to dry on instruments.

Observe cleaning agent use as indicated for automated and manual cleaning for instruments and accessories.

Manual Cleaning:

- **Use of low-alkaline detergent for all instruments with lumens. Manual cleaning NOT ALLOWED for the Articulating Arms. See automated cleaning below.**

Enzymatic cleaning agents, neutral pH cleaners, and soft-bristled brushes and soft pipe cleaners are recommended. If available, softened tap water is recommended for rinsing. Use a syringe to flush fluid through lumens. Use a soft-bristled brush to clean hard-to-reach areas. Use soft-bristled brushes, sponges, or cloths. Avoid steel wool. Use a soft-bristled brush to clean hard-to-reach areas. Use soft-bristled brushes, sponges, or cloths.

- Immediately after use, remove excess soil with a damp, lint-free cloth. Do not immerse instruments in a sink and let them soak.
- Rinse and flush instruments under running tap water for 3 minutes.
- Prepare enzymatic detergent solution according to the manufacturer's instructions. Use clean water to remove visible soil. Scrub inside any lumens or crevices. Scrub until all visible soil is removed.
- Using tap water, prepare an enzymatic cleaning solution according to the manufacturer's instructions, dilution recommendations, and temperature.
- Place instruments in the enzymatic cleaner, completely submerged, and soak for 45 - 60 minutes.
- Remove instruments from the enzymatic cleaner and rinse thoroughly under tap water. Flush lumens or cavities in the water stream. Rinse for 3 minutes.
- Using tap water, prepare a second enzymatic cleaning solution according to step 4.
- Ultrasonically clean instruments in the second enzymatic cleaning solution for 10 minutes. Use caution in the water stream. Rinse for 3 minutes.
- Repeat rinsing as in step 5, this time with de-ionized water for an additional 3 minutes.
- Dry with a soft, lint-free cloth or forced air.
- Inspect instruments for cleanliness. If any debris or contamination has been removed. If soil is present, repeat the cleaning process. Do not proceed with reprocessing of a soiled instrument.

Automated Cleaning:

Articulating Arms REQUIRE automated cleaning and control tightening knob must be tightened during cleaning. Do not completely loosen the control tightening knob during automated cleaning. Automated cleaning NOT ALLOWED for the Articulating Arms may use manual or automated cleaning.

- Rinse instruments with cold tap water for 3 minutes, ensure visible contamination is removed.
- Prepare detergent solution according to manufacturer's instructions.
- Load instruments into the washer-disinfector using a validated program.
- Run washer according to Thompson's validated cleaning cycle shown below.
- Inspect instruments for cleanliness following completion of cycle. If soil is present, repeat the cleaning process. Do not proceed with reprocessing of a soiled instrument.

Automated Enzymatic Cleaning

PHASE	TIME (MIN.)	TEMP.	DETERGENT/CONCENTRATION
Pre-Wash	2:00	<43°C (<109°F) Cold Tap Water	N/A
Enzyme Wash	01:00	Hot Tap Water	1% - 2 oz/gal)
Neutral pH Detergent	02:00	43°C (110°F) Softened	0.5% - 1 oz/gal)
Rinse 1	1:00	Hot Tap Water	N/A
Purified Water Rinse	00:10 (non-adjustable)	90°C (194°F) PURW	N/A
Drying	15:00 (adjustable)	116.5°C (240°F)	N/A

Note: Enzymatic cleaning cycle validated using Cavi® Enzymatic detergent and Reliance® Neutral pH detergent using manufacturer recommended concentrations. Cycle validated using Reliance® Neutral pH detergent using manufacturer recommended concentrations and proper according to manufacturer recommendation. The automated washer/disinfector manufacturer's instructions should be followed.

Automated Alkaline Cleaning *

PHASE	TIME (MIN.)	TEMP.	DETERGENT/ CONCENTRATION
Pre-Wash	2:00	<43°C (<109°F) Cold Tap Water	N/A
Pulsed Wash	01:00	Hot Tap Water	2.4 mL/L
Alkaline Wash - Rinse	4:00 -15	Hot Tap Water	N/A
Neutralizer Wash	1:00	60°C (140°F)	2.4 mL/L
Rinse	1:00	Hot Tap Water	N/A
Thermal Rinse	5:00	90°C (194°F) PURW	N/A
Drying	18:00 (adjustable)	116.5°C (240°F)	N/A

* Alkaline cleaning agents with a pH of 12 or less may be used to clean stainless steel and polymer instruments in counties where required by law or local ordinance. Alkaline cleaning agents are not approved for use with aluminum instruments. Alkaline cleaning agents are completely and thoroughly neutralized and rinsed from the devices or degradation may occur that limits the device life. Manufacturer's instructions for use of the alkaline detergent must be followed. Failure to do so may void warranty. Thompson Surgical Instruments, Inc. has validated alkaline cleaning agents may require this step. Refer to the manufacturer's recommendations for alkaline cleaning agents.

INSPECTION, MAINTENANCE, AND TESTING

Instruments must be inspected pre and post processing and prior to use. Inspection must include a visual and functional inspection of product integrity and cleanliness. Do not use damaged instruments. Damaged instruments may break during use, causing injury to the patient or surgeon.

- Carefully inspect instruments for damage, wear, and proper function before and after each cleaning cycle.
- Lubricate all moving mechanisms on instruments with a sterile, water-soluble product after every cleaning cycle. Consult manufacturer's instructions for use.
- Reassembly instruments, ensuring proper alignment of all components. Do not use instruments that appear damaged or broken (cracked, deformed, nonfunctional, or altered).
- Do not use instruments in which the laser markings are not visible (or both Thin Text and Zip Data Matrix). Using instruments in spite of invisible markings may result in patient injury or device failure.
- If sterilization instruments are identified, contact Thompson Surgical using the Product Complaints process.

STERILIZATION

- Prepare instruments for sterilization by wrapping in a sterilization wrap or placing in sterilization containers or removable parts where possible, without the use of tools.
- Arrange instruments in a manner that will promote exposure to steam sterilization can penetrate all surfaces.
- Wrap instruments or instrument tray in 2 layers of 1-ply polypropylene wrap, using sequential wrapping techniques. (ISO 11607-1).
- Sterilize instruments using one of the following cycles listed in the table below.
- Time "cool enough" is required prior to handling. Do not exceed 1 (Kg-(Cu) pounds). Weight per, and distribution must not exceed 2 lb or 1 Kg (2 pounds).

Sterilization - Outside USA

PRODUCT	METHOD	CYCLE	EXPOSURE TIME	MIN. DRY TIME
Thompson Retractor	Steam	Gravity	132°C (270°F) 4 Minutes	30 Minutes
		Prevacuum	132°C (270°F) 4 Minutes	30 Minutes ***

Sterilization - Outside EU

PRODUCT	METHOD	CYCLE	EXPOSURE TIME	MIN. DRY TIME
Thompson Retractor	Steam	Gravity	132°C (270°F) 4 Minutes	30 Minutes ***
		Prevacuum	132°C (270°F) *** 4 Minutes	30 Minutes ***

***** Extended drying times may be required depending on the load configuration, density, and sterilizer performance.**

The processing instructions provided herein are in accordance with EN ISO 17664 and EN ISO 17665 and have been validated as being capable of preparing non-sterile medical devices.

STORAGE:

Store in clean, dry conditions at room temperature.

DISPOSAL:

All products must be disposed of correctly and in accordance with local and national regulations and medical guidelines.

PRODUCT COMPLAINTS:

Refer to the Product Complaints process.

WARRANTY:

Thompson Surgical Instruments, Inc. warrants that it has been manufactured in accordance with local and national regulations and medical guidelines.

PRODUCT COMPLAINTS:

Notify in the event of any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user or patient is established.

WARRANTY:

Thompson Surgical Instruments, Inc. warrants that it has been manufactured in accordance with local and national regulations and medical guidelines.

If any Thompson product ever "malfunctions" and may have contributed to patient injury or death, Thompson should be notified immediately. When filing a complaint, please provide the following information: product name, lot number, the nature and extent of the complaint, and the nature of the complaint.

Instruments returned to Thompson Surgical Instruments should be hyperseal according to its IFU (Internet, sterilized before return.

MRI COMPATIBILITY STATEMENT:

The MR safety information was obtained through MR safety, efficacy, and/or compatibility in the MR environment. The safety of the Thompson Retractor in the MR environment has not been evaluated. The Thompson Retractor has not been tested for MR safety and has not been tested for MR compatibility.

For complete symbol definition, enter corresponding 4-digit code at https://www.ce-sign.info/en/

A summary of safety and clinical performance will be available at www.thompsonsurgical.com or on the Eudamed Database (when available).

THIS IS A REUSABLE DEVICE ONLY TO PRODUCTS MARKED "THOMPSON".

BG БЪЛГАРСКИ

Thompson Retractor за Medtronic®, произведен от Thompson Surgical Instruments, Inc.

ВАЖНИ ИНСТРУКЦИИ ЗА УПОТРЕБА НА THOMPSON RETRACTOR ЗА MEDTRONIC®

МОЛЯ, ПРОЧЕТЕТЕ ПРЕДИ УПОТРЕБА

Това инструкции за употреба са предназначени да помогнат на медицинските специалисти за безопасна употреба и правилно при боравене с Thompson Surgical Instruments, Inc. продукти. Thompson Surgical Instruments, Inc. препоръчва персоналът да бъде правилно обучен, почистен и дезинфекциран преди всяка употреба.

Thompson Surgical Instruments не премахва или ограничава крайната отговорност на потребителя за указанията и идентичността на всеки Thompson Surgical Instruments, Inc. продукт. Thompson Surgical Instruments, Inc. предоставя препоръки, които са доказали ефективност в клинична практика. Задължение на преработвателя е да спазва посочените инструкции.

Thompson Retractor не е предназначен за лечение или наблюдение на заболявания.

Неспазването на тези инструкции може да доведе до увреждане на пациента, да направи устройствата неизползваеми и да анулира гаранционните или сервизните договори.

ОПИСАНИЕ НА УСТРОЙСТВОТО

Thompson Retractor за Medtronic® е изделие за многократна употреба, предназначено да осигурява достъп и експозиция при различни хирургични процедури. Thompson Retractor за Medtronic® е произведен от неръждаема стомана и се доставя нестерилен. Той е наличен в различни анатомични размери и конфигурации.

ПРЕДНАЗНАЧЕНИЕ

Предвиденото изделие за пациенти, предназначени за хирургични процедури, може да варира в зависимост от извършваната процедура. Thompson Retractor за Medtronic® е предназначен за употреба от добре информирани лекари в подходящи за здравеопазване заведения. Предвиденото изделие за пациенти, предназначени за хирургични процедури, може да варира в зависимост от извършваната процедура. Thompson Retractor за Medtronic® е предназначен за употреба от добре информирани лекари в подходящи за здравеопазване заведения.

Sterilizzatrice - sz Amerikai Egyesült Államokban kívül

TERMÉK	MODSZER	CIKLUS	CIKLUS IDŐKE	EXPOZÍCIÓS IDŐ	MIN. SZÁRÍTÁSI IDŐ
Thompson Retractor	Gőz	Fertőtlenítés	132 °C (270 °F)	4 perc	30 perc ***

*** A szerelvény 135 °C-on történő sterilizálása esetén a minimális expozíciós idő 3 perc lehetővé válik.**
**** A szerelvény 121 °C-on történő sterilizálása esetén a minimális expozíciós idő 20 perc lehetővé válik.**
***** A szerelvény sterilizálása esetén a minimális szárítási idő 30 perc lehetővé válik.**

Olvassa el a sterilizáló készülék gyártójának ajánlásait a sterilizálási paraméterek tekintetében.

MEGJEGYZÉS: A sterilizáló vákuumos készülékre a 132 °C (270 °F) sterilizálási hőmérséklet a 4 perc lehetővé válik.

Az 44 megabit feldolgozási sebességű készülékek esetén az EN ISO 17664 és az EN ISO 17665 szabványok értelmében az ajánlott sterilizálási hőmérséklet a Thompson Surgical Instruments sterilizálási paraméterekhez a következőképpen történt változásokban.

TÁBLÁZAT:
Fém, műanyag nélkül, szobahőmérsékleten tárolandó.

ÁRTALMATLANÍTÁS:
Használat előtt ártalmatlanítsa a helyi és a nemzeti szabályozásoknak és egészségügyi irányelveknek megfelelően kell ártalmatlanítani.

A TERMÉKELLENŐRZÉS ÁTTEKINTÉSE:
Megjegyzés a felhasználónak vagy a betegnek: Az esetleges bajokat tapasztalt személyek minden súlyos vételár esemény jelentési kell a gyártónak és a helyi illetékes hatóságnak, amelyben a felhasználó és/vagy a beteg letelepedett.

A termék minőségének, megbízhatóságának, biztonságosságának, funkcionalitásának érdekében kizárólag felpárosítható eltávolítható egységek használhatók a Thompson Surgical Instruments által gyártott és forgalmazott szerelvényekkel.

Ön bármely Thompson szerelvénnyel „szemszögben” áll bent, ami hozzájárulhat a beteg vérellátásának megszakításához, ahonnan elvezetés kell a Thompson vállalattal.

A porosz kötőelemek lehúzják, vége meg az alkalmaz számok, kerülő, a gyártási lépést számok, az Ön nevét, telefonszámát, e-mail címét, a szervezete nevét az cinek és a porosz termékcsoportok kerülő.

MEGJEGYZÉS:
A szerelvényt ártalmi ipari vonatkozásban, a használóit műszereket a pálon használat utasításának megfelelően kell újrafeldolgozni minden új használat előtt.

MRI-KOMPATIBILITÁSI NYILATKOZAT:
Ezt az eszközt a Thompson az MR környezetben való biztonságosnak nem ismert, és ezt nem tesztelték a műszeres mező következtében a melegedési, vándorlási vagy elmozdulási veszélyek tekintetében.

A nemkívánatos hatás lehetséges következményei közé tartozik a képminőség és/vagy a spektroszkópiai adatok torzulása.

A biztonságosság és klinikai teljesítőképesség összefoglalása (SSCP) elérhető a www.thompsonsurgical.com weboldalon vagy az Eudamed adatbázisban (ha rendelkezésre áll).

A HASZNÁLATI UTASÍTÁS KIZÁRÓLAG A „THOMPSON” FELIRATTAL JELÖLT TERMÉKEKRE VONATKOZIK.

19 SLENSKA

Thompson Retractor for Medtronic®, framleitt af Thompson Surgical Instruments, Inc.

MIKILVÆGAR UPPLÝSINGAR FYRIR THOMPSON RETRACTOR FYRIR MEDTRONIC®

LESIÐ FYRIR NOTKUN

Vinsamlegast lesið leiðbeiningarnar er settið að sérhverju heilbrigðisstarfsfólki sem þyggja notkun og meðhöndlun, skoðuna vinnslu og viðhald fyrir Ø Thompson Retractor for Medtronic® skurðaðgerð og viðbúnaðar sukkhlíð. Nauðsynlegt er að skoða, hreinsa og smyrja sett áður en það er notað í fyrsta skipti.

Ef settið er ekki notað strax eftir hreinsun þá skoðið það aftur áður en það er notað til að tryggja að það sé hreint og virki rétt.

Settið hjá Thompson Surgical Instruments tekur sem notað eru á eldhúsmat skrifað. Í bindum þar sem endurvinnsluaðilar eru ábyrgir en þar sem notað er Medtronic® Thompson Retractor fyrir Medtronic® skurðaðgerð.

Thompson Retractor er eitið aðilaðar til að meðhöndla alla til að Thompson Surgical Instruments, Inc. Ekki er ábyrgð á notkun á vörum sem ekki eru framleiddar af Thompson Surgical Instruments, Inc. Ekki er ábyrgð á notkun á vörum sem ekki eru framleiddar af Thompson Surgical Instruments, Inc. Ekki er ábyrgð á notkun á vörum sem ekki eru framleiddar af Thompson Surgical Instruments, Inc.

FYRIRHUGUÐ NOTKUN

Thompson Retractor for Medtronic® er endurnotanlegt tæki sem er hannað til að vera notað og aðgang í þínu bone skurðaðgerðum. Thompson Retractor for Medtronic® er endurnotanlegt tæki sem er hannað til að vera notað og aðgang í skurðaðgerðum. Thompson Retractor for Medtronic® er endurnotanlegt tæki sem er hannað til að vera notað og aðgang í skurðaðgerðum, sérstök og skilvirk og aðgang í skurðaðgerðum.

FYRIRHUGUÐ NOTENDUR

Thompson Retractor for Medtronic® er endurnotanlegt tæki sem er hannað til að vera notað og aðgang í skurðaðgerðum, sérstök og skilvirk og aðgang í skurðaðgerðum.

FYRIRHUGUÐ SJÚKLINGAHÓPUR

Fyrirhugaðir sjúklingahópur samsvarandar af sjúklingum á hvaða aldri, stærð og kyn sem er, sem gangast undir skurðaðgerð sem skurðlæknir sem skurðlæknir sem skurðlæknir