PRODUCT NOTIFICATIONS

Medtronic

Medtronic Minimally Invasive Therapies Metallic Staple Composition Notification

In response to inquiries concerning possible allergic reactions to the staples and clips in Medtronic Minimally Invasive Therapies (formerly known as Surgical Solutions, Covidien) devices, the following information applies.

The composition of Minimally Invasive Therapies titanium and stainless steel clips and staples is:

Titanium		Stainless Steel	
Nitrogen	0.03%	Carbon	0.03%
Carbon	0.08%	Chrome	16.0 – 18.0%
Hydrogen	0.015%	Nickel	10.0 – 14.0%
Iron	0.20%	Manganese	2.0%
Oxygen	0.18%	Silicon	1.0%
Titanium	Balance	Sulfur	0.03%
		Phosphorus	0.045%
		Molybdenum	2.0 – 3.0%
		Iron	Balance

Minimally Invasive Therapies implantable titanium staples and clips are composed of titanium per ASTM F67 Grade 1. The above titanium composition **does not apply** to the implantable titanium components in the following devices due to the use of a titanium alloy instead:

- Titanium Tackers (ProTack™, Stat Tack™, and Tacker™ fixation devices)
- Herculon™ soft tissue reattachment system
- Ogden™ soft tissue reattachment system

The above titanium composition also does not apply to the implantable titanium components in the following device due to the use of titanium per ASTM F67 Grade 2 instead:

- ChemoSite™ infusion port products

The following devices apply stainless steel staples or clips:

- Premium GIA™ 50 and 90 single use loading units
- PI™ single use loading units
- LDS™ 15L single use loading unit
- Royal™, Concord™, SM™, Signet™, MultiFire Premium™, DFS™, and Appose™ skin staplers

Biocompatibility testing has been performed to a level appropriate for permanent implant on both titanium and stainless steel with no adverse effects noted, and there is a long history of safety and efficacy for both materials as implants.

Many of our devices contain stainless steel components that may have short term patient contact during a procedure. All of these components (such as anvils, jaws, shafts and blades) have been tested for short term contact indicative of use during a procedure.

Depending on the type of stainless steel used in these components, the nickel content may be up to 18% by weight.

If a patient presents concerns about metal allergies, the appropriate allergy screenings may be indicated. Please note that the above information does not, and that Minimally Invasive Therapies cannot, state, indicate, or imply that Minimally Invasive Therapies staples or clips will not induce some type of reaction in any particular patient.

We hope this information addresses your concerns.

Should you have any further questions, please contact Customer Service at customerservice@covidien.com or 1-800-962-9888, option 2.

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Magnetic Resonance Imaging (MRI) and Nuclear Magnetic Resonance (NMR) Procedures

To Whom It May Concern:

MRI INFORMATION

The [implantable component] in the [product family] are MR conditional.

MR Conditional

Static Magnetic Field

Non-clinical testing demonstrated that a representative [implantable component] is MR conditional. A patient with these [implantable components] can be scanned safely immediately after placement of the [implantable component] under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of [maximum spatial gradient]
- Normal Operating Mode of operation for the MRI system (whole body averaged SAR, 2-W/kg) for 15 minutes of scanning, per pulse sequence

MRI Related Heating

Under the scan conditions defined above, the Steel suture is expected to produce a maximum temperature rise of less than [highest temperature change] after 15 minutes of continuous scanning.

Artifact Information

In non-clinical testing, the image artifact caused by the [implantable component] extends approximately [insert distance] mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

Product Family	Implantable Component	Highest Temperature Change	Image Artifact Distance	Maximum Spatial Gradient
LDS, PLDS[1]	Titanium Staple	3.2°C	2 mm	3000-Gauss/cm or less
EEA, CEEA[1]	Titanium Staple	3.2°C	2 mm	3000-Gauss/cm or less
TA, PMFTA[1]	Titanium Staple	3.2°C	2 mm	3000-Gauss/cm or less
ENDO GIA, DST GIA[1]	Titanium Staple	3.2°C	2 mm	3000-Gauss/cm or less
ILA[1]	Titanium Staple	3.2°C	2 mm	3000-Gauss/cm or less
Roticulator[1]	Titanium Staple	3.2°C	2 mm	3000-Gauss/cm or less
PI Stapler[1]	Titanium Staple	3.2°C	2 mm	3000-Gauss/cm or less
Endo Hernia[1]	Titanium Staple	3.2°C	2 mm	3000-Gauss/cm or less
Reliamax[1]	Titanium Staple	3.2°C	2 mm	3000-Gauss/cm or less

GIA Premium[2]	Stainless Steel Staple	3.3°C	2 mm	3000-Gauss/cm or less
PI DLU[2]	Stainless Steel Staple	3.3°C	2 mm	3000-Gauss/cm or less
MultiFire Premium[2]	Stainless Steel Staple	3.3°C	2 mm	3000-Gauss/cm or less
Signet[2]	Stainless Steel Staple	3.3°C	2 mm	3000-Gauss/cm or less
Appose[2]	Stainless Steel Staple	3.3°C	2 mm	3000-Gauss/cm or less
SM 35[2]	Stainless Steel Staple	3.3°C	2 mm	3000-Gauss/cm or less
DFS[2]	Stainless Steel Staple	3.3°C	2 mm	3000-Gauss/cm or less
Purstring[2]	Stainless Steel Staple	3.3°C	2 mm	3000-Gauss/cm or less
Endo Clip[3]	Titanium Clip	2.2°C	6 mm	3000-Gauss/cm or less
Premium Surgiclip[3]	Titanium Clip	2.2°C	6 mm	3000-Gauss/cm or less
AcuClip[3]	Titanium Clip	2.2°C	6 mm	3000-Gauss/cm or less
MultApplier[3]	Titanium Clip	2.2°C	6 mm	3000-Gauss/cm or less
Herculon[4]	Titanium Anchor	2.8°C	18 mm	3000-Gauss/cm or less
Stat Tack[5]	Titanium Tack	1.6°C	7 mm	23400-Gauss/cm or less
Tacker[5]	Titanium Tack	1.6°C	7 mm	23400-Gauss/cm or less
Protack[5]	Titanium Tack	1.6°C	7 mm	23400-Gauss/cm or less
Steel Suture[6]	Stainless Steel Suture	9.4°C	24 mm	2360-Gauss/cm or less

[1] Chen, Ji. Evaluation of Magnetic Field Interactions, Heating and Artifacts for Medtronic Circular Staple (July 21, 2016)

[2] Chen, Ji. Evaluation of Magnetic Field Interactions, Heating and Artifacts for Medtronic PI Staple (August 1, 2016)

[3] Chen, Ji. Evaluation of Magnetic Field Interactions, Heating and Artifacts for Medtronic SurgiClip (July 21, 2016)

[4] Chen, Ji. Evaluation of Magnetic Field Interactions, Heating and Artifacts for Medtronic Herculon Soft Tissue Reattachment Suture Anchor (July 21, 2016)

[5]Chen, Ji. Evaluation of Magnetic Field Interactions, Heating, and Artifacts for the ProTack Fastener from Covidien ProTack AutoSuture Fixation Device (September 13, 2017)

[6] Chen, Ji. Evaluation of Magnetic Field Interactions, Heating and Artifacts for Medtronic Nonabsorbable Suture (December 13, 2017)

MRI INFORMATION

The [implantable component] in the [product family] are MR conditional.

Static Magnetic Field

Non-clinical testing demonstrated that a representative [implantable component] is MR conditional. A patient with these [implantable components] can be scanned safely immediately after placement of the [implantable component] under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less

MRI Related Heating

In non-clinical testing, the titanium clip produced the following temperature rise during MRI performed for 15 minutes in the 3-Tesla (3 Tesla/128 MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

Highest temperature change: + [insert temperature]° C

Therefore, the MRI related heating experiments for the titanium clip at 3 Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9-W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in associated with these specific conditions was equal to or less than + [insert temperature]° C after 15 minutes of continuous scanning.

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the [implantable component]. Therefore, optimization of MR imaging parameters to compensate for the presence of this [implantable component] may be necessary.

Product Family	Implantable Component		Highest Temperature Change		Whole Body Average Temperature Change
Chemosite	Titanium Port		1.6°C		1.8°C
Pulse Sequence	***T1-SE***	**T1-SE**	**GRE**	**GRE**	
Signal Void Size	1,211 mm^2	975 mm^2	2,405 mm^2	1,839 mm^2	
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular	

Shellock, Frank. Evaluation of Magnetic Field Interactions, Heating, and Artifacts at 3-Tesla for Products from Covidien.

Please note that this does not apply to the following:

- Stainless steel staples/sutures or other stainless steel items that may have a greater mass than the current Covidien stainless steel staples/sutures.
- Exposure to static fields greater than 3.0 Tesla
- Use of magnetic materials such as suture needles
- Items not manufactured or distributed by Covidien
- Flexon™ Cardiac Pacing Leads

Do not perform magnetic resonance procedures if tissue integrity and implant's ability to remain properly attached are of concern, or if proper identification of the implant location cannot be obtained.

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Latex Product Notification

To Whom It May Concern:

With the exception of the devices listed below, all other Medtronic Minimally Invasive Therapies surgical devices are not made with natural rubber latex. The packaging used for the Medtronic Minimally Invasive Therapies surgical devices is not made with natural rubber latex.

The following devices have been identified to contain latex:

- The Blunt Tip Trocar products, (Reorder Codes: OMST10BT, OMST10BTS, OMST12BT)
- SEPS products using the balloon anchoring system, (Reorder Codes: VBT240T, VBT300, SMBTTRND, and SMBTTOVL)
    - The latex in the listed reorder codes 1 and 2 is the base material of the trocar balloon, which is encapsulated in a silicone rubber material. In normal use there is no patient contact. In the unlikely event of a balloon rupture, the latex may come into contact with the patient.
- The AcuClip™ device (OMSA8) includes latex tubing enclosed in the handle, which does not come in contact with the patient at any time.

All other Medtronic Minimally Invasive Therapies surgical devices do not contain any latex. None of the packaging used for the Medtronic Minimally Invasive Therapies surgical devices contain latex.

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DEHP Product Notification

To Whom It May Concern:

Reorder codes EEAORVIL21A (EEA DST Series Orvil 21mm) and EEAORVIL25A (EEA DST Series Orvil 25 mm) contain PVC but do not have DEHP. Below is the comprehensive list of products containing PVC with DEHP.

120059	Chemosite™ venous access 8" line ext, 22 gauge
120068	Chemosite™ venous access 8" line ext, 22 gauge
120069	Chemosite™ venous access 8" line ext, 20 gauge
120072	Chemosite™ venous access 8" line ext, 22 gauge
120073	Chemosite™ venous access 8" line ext, 20 gauge
120074	Chemosite™ venous access 8" line ext, 19 gauge
120075	Chemosite™ venous access 8" line ext, 19 gauge
120076	Chemosite™ venous access 8" line ext, 19 gauge
120077	Chemosite™ venous access 8" line ext, 20 gauge
178081	Surgiwand™ II 5 mm Suction/Irrigator - Suction/irrigation device without tubing.
178082	Surgiwand™ II 5 mm Suction/Irrigator - Suction/irrigation device with tubing EPS-34 cm
178083	Surgiwand™ II 5 mm Suction/Irrigator - Suction/irrigation device with tubing GFS-34 cm
178091	Surgiwand™ II 5 mm w/Caut/L-Hook
178092	Surgiwand™ II 5 mm w/Caut/L-Hook/Tube/EPS
178093	Surgiwand™ II 5 mm w/Caut/L-Hook/Tube/GFS
178094	Surgiwand™ II 5 mm w/Caut/Spatula/Tub/GFS
178095	Surgiwand™ II 5 mm w/CAUT/Spatula/Tube/EPS
898500	Snowden Pencer™ Breast Balloon DISS 900ml
898501	Snowden Pencer™ Breast Balloon DISCT 1000ML
OMSXB1	Spacemaker™ Extra View Balloon - Round
OMSXB2	Spacemaker™ Extra View Balloon - Oval
SMKDN	Spacemaker™ Dissection Balloon - Kidney
SMOVL	Spacemaker™ Dissection Balloon - Oval
SMRND	Spacemaker™ Dissection Balloon - Round
SMSBT	Spacemaker™ Structural Balloon Trocar
SMBTTOVL	Spacemaker™ Plus BTT/Oval Balloon Dissector
SMBTTRND	Spacemaker™ Plus BTT/Round Balloon Dissector
SMSBTOVL	Spacemaker™ Plus SBT/Oval Balloon Dissector
SMSBTRND	Spacemaker™ Plus SBT/Round Balloon Dissector
SMBTTRNDX	Spacemaker™ Pro BTT and Round
SMBTTOVLX	Spacemaker™ Pro BTT and Oval
SMSBTRNDX	Spacemaker™ Pro SBT and Round
SMSBTOVLX	Spacemaker™ Pro SBT and Oval
171312	Miniport™ 2 mm Sleeve w/Insufflation
171313	Miniport™ 2 mm Introducer w/Insufflation
171315	Miniport™ 2 mm Introducer - Short
171317	Miniport™ 2 mm Sleeve - Short
8886827906	Vital Vue™ System, Yankauer-Bulb Tip
8886828006	Vital Vue™ System, Extended Yankauer-Bulb Tip
8886828106	Vital Vue™ System, Extended Yankauer-Slender Tip
8886828206	Vital Vue™ System, Yankauer Type Shape
8886828306	Vital Vue™ System, Extra Long Orthopedic Tip

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Teflon White Powder Residue Product Notification

To Whom It May Concern:

Some of our customers have expressed concern over a white powder residue sometimes seen on various Medtronic products (formerly known as Covidien) including TA*, LDS*, EEA*, Surgiclip*, GIA*, ILA*, PI*, Premium*, Concorde*, Signet*, Appose*, SM*, DFS*, Tacker*, Absorbable stapling devices and all Endo stapling devices. This is the result of a lubrication process in which the device may be dipped or sprayed with a polytetraflouroethylene (PTFE) solution. Once dried, the PTFE remains on the assembly, and may leave a small amount of white powder residue. This PTFE lubricant aids the proper functioning of the device.

PTFE is well characterized, having been used in implantation since the 1950's. It has been implanted in many patients, with some implant durations going well beyond 20 years. PTFE is inert and is encapsulated by the body.

The following are some examples of long-term implant devices containing Teflon (PTFE);

Cardiac Valves	Catheter Material	Craniomaxillofacial Reconstruction Material
Abdominal Wall Mesh	Vascular Grafts	Pledgets

While there have been some inquiries about the appearance of the lubricant residue, there have been no confirmed patient injuries or device failures related to it.

Furthermore, there have been no patient injuries or patient complaints related to the white lubricant powder since the inception of the devices for greater than 20 years. There have been some documented visual complaints from some surgeons and nurses regarding the white lubricant powder.

An example would be from the Surgiclip™ product line where at least 500,000 devices have been manufactured annually over those 20 years. That is over 10 million devices. This year alone it is estimated that we will make over 700,000 Premium Surgiclip™ devices.

The following biocompatibility tests have been performed by Medtronic on Polytetraflouroethylene (PTFE) with acceptable results:

Cytotoxicity
Acute Systemic Toxicity
Hemolysis
Thrombogenicity
Pyrogenicity
Sensitivity
Vaginal Irritation
Mutagenicity
7, 30, 60, 90 and 173 day implants
Intracutaneous Irritation

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