

To whom it may concern

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Sweden
April 12, 2018
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MR SAFETY INFORMATION

It is hereby certified that products manufactured by ATOS MEDICAL AB, P. O. Box 183, SE-242 22 HÖRBY, Sweden, listed down below are considered to be MR-safe.

The Provox Vega Voice Prostheses, supplied by Atos Medical AB, are electrically nonconductive, nonmetallic, and nonmagnetic and have therefore no potential for interaction with the MR-field. They are solely manufactured by plastic material and silicone rubber and therefore the devices are considered to be MR-safe, as defined in ASTM F2503.

Provox Vega Incl. Provox Insertion system

REF	Denomination	MR status
4270 through 4287	Provox Vega XXFr YYmm	MR-safe
8270 through 8287	Provox Vega XXFr YYmm	MR-safe
4288 through 4305	Provox Vega XtraSeal XXFr YYmm	MR-safe
8288 through 8305	Provox Vega XtraSeal XXFr YYmm	MR-safe

**Note: The Voice Prostheses are available in three different diameters, (17, 20 and 22.5Fr) here marked with XX. The Voice prostheses are also available in 6 different lengths, 4, 6, 8, 10, 12.5 and 15mm, here marked YY.*

Hörby 2018-04-12

ATOS MEDICAL AB



Mikael Melefors, PhD
Vice President Design & Development

At Atos Medical, we are committed to giving a voice to people who breathe through a stoma, with design solutions and technologies built on decades of experience and a deep understanding of our users.

www.atosmedical.com

MR-Safety information ProTrach DualCare System

The following included in the ProTrach DualCare System, supplied by Atos Medical AB, are electrically nonconductive, nonmetallic, and nonmagnetic and have therefore no potential for interaction with the MR field. They are solely manufactured by plastic material, silicone rubber and silicone-based glue and therefore the devices are considered to be **MR-safe**, as defined in ASTM F2503. The individual materials can be found in the products Technical Information.

The ProTrach DualCare System

REF	Name	MR status
7741	ProTrach DualCare Set 15	MR-Safe
7740	ProTrach DualCare Set 22	MR-Safe
7744	ProTrach DualCare Speaking Valve	MR-Safe
7755	ProTrach DualCare Speaking Valve Blue	MR-Safe
7742	ProTrach HME 15 Regular	MR-Safe
7743	ProTrach HME 15 Regular (BigPack)	MR-Safe
7747	ProTrach HME 22 Regular	MR-Safe
7745	Removal Aid	MR-Safe
7756	HME DigiTop O2	MR-Safe
7746	ProTrach Connection strap	MR-Safe

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Rolf Karlberg
 Vice President Development & Operations

2024-04-09
 Date

MR-Safety information Provox Accessories

The following Provox Accessories, supplied by Atos Medical AB, are electrically nonconductive, nonmetallic, and nonmagnetic and have therefore no potential for interaction with the MR field. They are solely manufactured by plastic material and silicone rubber and therefore the devices are considered to be **MR-safe**, as defined in ASTM F2503. The individual materials can be found in the products Technical Information.

The Provox Accessories

REF	Name	MR status
8119	Provox Vega Plug 17	MR-Safe
8129	Provox Vega Plug 20	MR-Safe
8139	Provox Vega Plug 22.5	MR-Safe
8109	Provox Flush	MR-Safe
7122	Provox Dilator 17	MR-Safe
7123	Provox Dilator 20	MR-Safe
7211	Provox Dilator	MR-Safe
7275	Provox XtraFlange 22,5	MR-Safe
7276	Provox XtraFlange 20	MR-Safe
7277	Provox XtraFlange 17	MR-Safe

The following Provox Accessories, supplied by Atos Medical AB are considered to be **MR-Unsafe**, since they contain metallic components that have potential of interfering with the MR-field, or if the product only can be used in combination with products containing metallic components. The individual materials can be found in the products Technical Information.

The Provox Accessories

REF	Name	MR status
7204	Provox Brush, 6 pcs	MR-Unsafe
7225	Provox Brush XL, 6 pcs	MR-Unsafe
7205	Provox Plug incl. 1 brush	MR-Unsafe
7215	Provox Guide Wire	MR-Unsafe
7210	Provox Pharynx Protector	MR-Unsafe
7203	Provox Trocar	MR-Unsafe
7270	Provox Measure	MR-Unsafe
7271	Provox Measure Flanges	MR-Unsafe

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Vice President Development & Operations

2024-02-21

Date

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MR-Safety information Provox ActiValve System

The Provox ActiValve Prosthesis, supplied by Atos Medical AB, are considered to be **MR-Unsafe** since they contain magnetic and metallic components that have potential of interfering with the MR-field. Experimental data from tests with Provox ActiValve have shown that for the patient there is no risk of device dislocation (tested up to 1,5 Tesla). However, an area of at least 3 cm around the prosthesis will not be reliably depicted.

The magnets in Provox ActiValve may be affected by MRI which can cause leakage through the prosthesis. If the Provox ActiValve is in place during MRI, ensure proper function after the MR procedure

The individual materials can be found in the products Technical Information. Since the ActiValve Lubricant is part of the Provox ActiValve System and is only used when utilizing a ActiValve prosthesis this product is also considered to be MR-Unsafe. The MR status is solely concerning the voice prosthesis and does not cover any accessories that are accompanying the voice prosthesis. Information about accessories can be found in *MR-Safety information Provox Accessories*.

The Provox ActiValve System

REF	Name	MR Status
7150, 7160, 7165	Provox ActiValve 4,5 mm	MR-Unsafe
7151, 7161, 7166	Provox ActiValve 6 mm	MR-Unsafe
7152, 7162, 7167	Provox ActiValve 8 mm	MR-Unsafe
7153, 7163, 7168	Provox ActiValve 10 mm	MR-Unsafe
7154, 7164, 7169	Provox ActiValve 12,5 mm	MR-Unsafe
7149	ActiValve Lubricant	MR-Unsafe

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2014-02-21
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MR-Safety information Provox FreeHands HME

The following included in the Provox FreeHands HME system, supplied by Atos Medical AB are considered to be **MR-Unsafe**, since they contain metallic components that have potential of interfering with the MR-field. Since the cleaning and storage box listed below, is only used when utilizing a FreeHands device these products are also considered to be MR-Unsafe. The individual materials can be found in the products Technical Information.

The Provox FreeHands HME

REF	Name	MR status
7710	Provox FreeHands HME (whole set)	MR-Unsafe
7713	Provox FreeHands HME Speech Valve Membrane Light	MR-Unsafe
7714	Provox FreeHands HME Speech Valve Membrane Medium	MR-Unsafe
7715	Provox FreeHands HME Speech Valve Membrane Strong	MR-Unsafe
7718	Provox FreeHands HME Cleaning and Storage Box	MR-Unsafe
7719	Provox FreeHands HME Adjustment Kit	MR-Unsafe
7730	Provox HME Cap	MR-Unsafe
7716	Provox FreeHands HME Replacement Device, light	MR-Unsafe
7717	Provox FreeHands HME Replacement Device, medium	MR-Unsafe
7721	Provox FreeHands HME Replacement Device, strong	MR-Unsafe
7722	Provox FreeHands HME Replacement Device	MR-Unsafe

The following included in the Provox FreeHands HME system, supplied by Atos Medical AB, are electrically nonconductive, nonmetallic, and nonmagnetic and have therefore no potential for interaction with the MR field. They are solely manufactured by plastic material, silicone rubber and silicone-based glue and therefore the devices are considered to be **MR-safe**, as defined in ASTM F2503. The individual materials can be found in the products Technical Information.

The Provox FreeHands HME

REF	Name	MR status
7711	Provox FreeHands HME Cassette, 30 pc*	MR-Safe
7712	Provox FreeHands HME Cassette, 20 pc*	MR-Safe
7720	Provox Silicone Glue	MR-Safe
8161	Provox FreeHands FlexiVoice Light	MR-Safe
8162	Provox FreeHands FlexiVoice Medium	MR-Safe
8163	Provox FreeHands FlexiVoice Strong	MR-Safe
7757	Provox FreeHands FlexiVoice Set Plus	MR-Safe
7760	Provox FreeHands FlexiVoice Set	MR-Safe

*Provox FreeHands HME Cassette must not be used without first being properly attached to the FreeHands device.

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2014-04-09

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MR-Safety information Provox NID Voice Prosthesis System

The Provox NID Voice Prosthesis System, supplied by Atos Medical AB, are electrically nonconductive, nonmetallic, and nonmagnetic and have therefore no potential for interaction with the MR field. They are solely manufactured by plastic material and silicone rubber and therefore the devices are considered to be **MR-safe**, as defined in ASTM F2503.

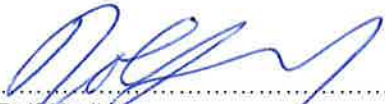
Tests have been performed showing that Provox2 is fully MRI compatible in a 3 Tesla Philips Achieva. This test is also valid for Provox NID.

The individual materials can be found in the products Technical Information. The MR status is solely concerning the voice prosthesis and does not cover any accessories that are accompanying the voice prosthesis. Information about accessories can be found in *MR-Safety information Provox Accessories*.

The Provox NID Voice Prosthesis System

REF	Name	MR Status
7101	Provox NID 17, 6mm	MR-Safe
7102	Provox NID 17, 8mm	MR-Safe
7103	Provox NID 17, 10mm	MR-Safe
7104	Provox NID 17, 12mm	MR-Safe
7105	Provox NID 17, 14mm	MR-Safe
7106	Provox NID 17, 18mm	MR-Safe
7111	Provox NID 20, 6mm	MR-Safe
7112	Provox NID 20, 8mm	MR-Safe
7113	Provox NID 20, 10mm	MR-Safe
7114	Provox NID 20, 12mm	MR-Safe
7115	Provox NID 20, 14mm	MR-Safe
7116	Provox NID 20, 18mm	MR-Safe
7128	Provox NID Storage Box	MR-Safe

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MR-Safety information Provox Pulmonary Rehabilitation Products

The following Pulmonary Rehabilitation products, supplied by Atos Medical AB are electrically nonconductive, nonmetallic, and nonmagnetic and have therefore no potential for interaction with the MR field. They are solely manufactured by plastic material and therefore the devices are considered to be **MR-safe**, as defined in ASTM F2503. The individual materials can be found in the products Technical Information.

The Provox Pulmonary Rehabilitation Products

REF	Name	MR status
7240, 7241	Provox HME Cassette (20 pc)	MR-Safe
7242, 7243	Provox HME Cassette (30 pc)	MR-Safe
7240C, 7241C	Provox HME Cassette (20 pc)	MR-Safe
7242C, 7243C	Provox HME Cassette (30 pc)	MR-Safe
7236	HME Compact, Normal	MR-Safe
7237	HME Compact, HiFlow	MR-Safe
7238	HME Compact, Starterkit	MR-Safe
7247	Provox Micron HME (5 pc)	MR-Safe
7248	Provox Micron HME (30 pc)	MR-Safe
7297	Provox XtraMoist HME (5 pc)	MR-Safe
7298	Provox XtraFlow HME (5 pc)	MR-Safe
7290	Provox XtraMoist HME (30 pc)	MR-Safe
7291	Provox XtraFlow HME (30 pc)	MR-Safe
7266	Provox XtraMoist HME (90 pc)	MR-Safe
7267	Provox XtraFlow HME (90 pc)	MR-Safe
7244	Provox Cleaning Towel	MR-Safe
7251	Provox Adhesive Regular Round	MR-Safe
7252	Provox Adhesive Regular Oval	MR-Safe
7253	Provox Adhesive FlexiDerm Round	MR-Safe
7254	Provox Adhesive FlexiDerm Oval	MR-Safe
7255	Provox Adhesive OptiDerm Round	MR-Safe
7256	Provox Adhesive OptiDerm Oval	MR-Safe
7257	HME Let's Start Sample Bag	MR-Safe
7265	Provox XtraBase	MR-Safe
7289	Provox StabiliBase (15 pc)	MR-Safe
7299	Plastic/Acrylic Adhesive	MR-Safe
7318	Provox StabiliBase OptiDerm (15 pc)	MR-Safe
7328	Provox StabiliBase OptiDerm (5 pc)	MR-Safe
7250	Provox HME StarterKit	MR-Safe
7601,7602,7603,7605, 7606,7607,7609,7610, 7611,7613,7614,7615, 7624,7625,7626,7627, 7628,7629,7630,7631, 7637,7638,7640,7641, 7643,7644, 7646, 7647	Provox LaryTube	MR-Safe
7648	Provox LaryTube Sizer Kit	MR-Safe

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7671, 7672, 7673,7674	Provox LaryButton 8mm	MR-Safe
7685, 7686, 7687,7688	Provox LaryButton 18mm	MR-Safe
7669	Provox LaryClip	MR-Safe
7690	Provox LaryButton Sizer Kit	MR-Safe
7668	Provox TubeHolder	MR-Safe
7246	Provox HME CassetteAdaptor	MR-Safe
7260	Provox ShowerAid	MR-Safe
7263	Provox BasePlate Adaptor	MR-Safe
7330	Provox Adhesive Regular Plus	MR-Safe
7331	Provox Adhesive FlexiDerm Plus	MR-Safe
7332	Provox Adhesive OptiDerm Plus	MR-Safe

The following Pulmonary Rehabilitation products, supplied by Atos Medical AB are considered to be **MR-Unsafe**, since they contain metallic components that have potential of interfering with the MR-field. The individual materials can be found in the products Technical Information.

The Provox Pulmonary Rehabilitation Products

REF	Name	MR status
7660, 7661	Provox TubeBrush	MR-Unsafe
7654	Provox Fenestration Punch	MR-Unsafe

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2016-02-21
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MR-Safety information Provox Trach-HME Products

The Trach-HME products, supplied by Atos Medical AB are electrically nonconductive, nonmetallic, and nonmagnetic and have therefore no potential for interaction with the MR field. They are solely manufactured by plastic material and therefore the devices are considered to be **MR-safe**, as defined in ASTM F2503. The individual materials can be found in the products Technical Information.

The Provox Trach-HME Products

REF	Name	MR Status
7704	TrachPhone	MR-Safe
7705	MEDIFLUX HCH F6	MR-Safe
7707	TrachPhone 30 pcs	MR-Safe

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2024-02-21
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MR-Safety information Provox Vega System

The Provox Vega Prothesis, supplied by Atos Medical AB, are electrically nonconductive, nonmetallic, and nonmagnetic and have therefore no potential for interaction with the MR field. They are solely manufactured by plastic material and silicone rubber and therefore the devices are considered to be **MR-safe**, as defined in ASTM F2503.

Tests have been performed showing that Provox Vega prosthesis is fully MRI compatible in a 3 Tesla Philips Achieva.

The individual materials can be found in the products Technical Information. The MR status is solely concerning the voice prosthesis and does not cover any accessories that are accompanying the voice prosthesis. Information about accessories can be found in *MR-Safety information Provox Accessories*.

The Provox Vega System

REF	Name	MR status
8110-X	Provox Vega 17Fr, 4 mm	MR-Safe
8111-X	Provox Vega 17Fr, 6 mm	MR-Safe
8112-X	Provox Vega 17Fr, 8 mm	MR-Safe
8113-X	Provox Vega 17Fr, 10 mm	MR-Safe
8114-X	Provox Vega 17Fr, 12.5 mm	MR-Safe
8115-X	Provox Vega 17Fr, 15 mm	MR-Safe
8120-X	Provox Vega 20Fr, 4 mm	MR-Safe
8121-X	Provox Vega 20Fr, 6 mm	MR-Safe
8122-X	Provox Vega 20Fr, 8 mm	MR-Safe
8123-X	Provox Vega 20Fr, 10 mm	MR-Safe
8124-X	Provox Vega 20Fr, 12.5 mm	MR-Safe
8125-X	Provox Vega 20Fr, 15 mm	MR-Safe
8130-X	Provox Vega 22.5Fr, 4 mm	MR-Safe
8131-X	Provox Vega 22.5Fr, 6 mm	MR-Safe
8132-X	Provox Vega 22.5Fr, 8 mm	MR-Safe
8133-X	Provox Vega 22.5Fr, 10 mm	MR-Safe
8134-X	Provox Vega 22.5Fr, 12.5 mm	MR-Safe
8135-X	Provox Vega 22.5Fr, 15 mm	MR-Safe

-X stands for different language versions (1,2,3 etc), but it is the same product.

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The Provox Vega Puncture Set, supplied by Atos Medical AB are considered to be **MR-Unsafe**, since they contain metallic components that have potential of interfering with the MR-field. The safety of the Provox Vega prosthesis is stated above. The individual materials can be found in the products Technical Information.

The Provox Vega System

REF	Name	MR status
8140-X	Provox Vega Puncture Set 17Fr 8mm	MR-Unsafe
8141-X	Provox Vega Puncture Set 17Fr 10mm	MR-Unsafe
8142-X	Provox Vega Puncture Set 17Fr 12,5mm	MR-Unsafe
8143-X	Provox Vega Puncture Set 17Fr 15mm	MR-Unsafe
8144-X	Provox Vega Puncture Set 20Fr 8mm	MR-Unsafe
8145-X	Provox Vega Puncture Set 20Fr 10mm	MR-Unsafe
8146-X	Provox Vega Puncture Set 20Fr 12,5mm	MR-Unsafe
8147-X	Provox Vega Puncture Set 22,5Fr 8mm	MR-Unsafe
8148-X	Provox Vega Puncture Set 22,5Fr 10mm	MR-Unsafe
8149-X	Provox Vega Puncture Set 22,5Fr 12,5mm	MR-Unsafe

-X stands for different language versions (1,2,3 etc), but it is the same product.

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MR-Safety information Provox Voice Prosthesis System

The Provox Voice Prosthesis System, supplied by Atos Medical AB, are electrically nonconductive, nonmetallic, and nonmagnetic and have therefore no potential for interaction with the MR field. They are solely manufactured by plastic material and silicone rubber and therefore the devices are considered to be **MR-safe**, as defined in ASTM F2503.

Tests have been performed showing that Provox2 is fully MRI compatible in a 3 Tesla Philips Achieva. This test is also valid for Provox1.

The individual materials can be found in the products Technical Information. The MR status is solely concerning the voice prosthesis and does not cover any accessories that are accompanying the voice prosthesis. Information about accessories can be found in *MR-Safety information Provox Accessories*.

The Provox Voice Prosthesis System

REF	Name	MR Status
7208	Provox 4,5mm	MR Safe
7200	Provox, 6 mm	MR Safe
7201	Provox 8 mm	MR Safe
7202	Provox, 10 mm	MR Safe

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MR-Safety information Provox2 Voice Prosthesis System

The Provox2 Voice Prosthesis System, supplied by Atos Medical AB, are electrically nonconductive, nonmetallic, and nonmagnetic and have therefore no potential for interaction with the MR field. They are solely manufactured by plastic material and silicone rubber and therefore the devices are considered to be **MR-safe**, as defined in ASTM F2503.

Tests have been performed showing that Provox2 is fully MRI compatible in a 3 Tesla Philips Achieva.

The individual materials can be found in the products Technical Information. The MR status is solely concerning the voice prosthesis and does not cover any accessories that are accompanying the voice prosthesis. Information about accessories can be found in *MR-Safety information Provox Accessories*.

The Provox2 Voice Prosthesis System

REF	Name	MR statu
7216 -X	Provox2 4,5 mm	MR Safe
7217 -X	Provox2 6 mm	MR Safe
7218 -X	Provox2 8 mm	MR Safe
7219 -X	Provox2 10 mm	MR Safe
7221 -X	Provox2 12,5 mm	MR Safe
7224 -X	Provox2 15 mm	MR Safe
7223 -X	Provox2 StarterKit	MR Safe

-X stands for different language versions (1, 2, 3, 4, 5 etc), but is the same product.

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MR-Safety information Rhinology Products

The Rhinology products, supplied by Atos Medical AB are electrically nonconductive, nonmetallic, and nonmagnetic and have therefore no potential for interaction with the MR field. They are solely manufactured by plastic material and silicone rubber and therefore the devices are considered to be **MR-safe**, as defined in ASTM F2503. The individual materials can be found in the products Technical Information.

The Rhinology Products

REF	Name	MR Status
7370	Nasal Vent Splint	MR-Safe
7350	Nasal Splint Small 0.25	MR-Safe
7355	Nasal Splint Small 0.50	MR-Safe
7360	Nasal Splint Large 0.25	MR-Safe
7365	Nasal Splint Large 0.50	MR-Safe
7352	Nasal Splint Sheeting 0.25	MR-Safe
7366	Nasal Splint Sheeting 0.50	MR-Safe
7353	Silicone Sheeting	MR-Safe
7354	Silicone Sheeting, reinforced	MR-Safe
7451, 7452	Silicone Sheeting	MR-Safe
7455, 7456, 7457, 7458, 7459	Silatos Silicone Sheeting	MR-Safe
7367	Nasofix Thermo, Small	MR-Safe
7368	Nasofix Thermo, Large	MR-Safe
7369	Nasofix Thermo, Custom-cut	MR-Safe
7380	Septal Button	MR-Safe

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2019-02-21
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MR-Safety information SinoJect System

The SinoJect Instruments and SinoJect Rods Set, included in the SinoJect System, supplied by Atos Medical AB are considered to be **MR-Unsafe**, since they contain metallic components that have potential of interfering with the MR-field. The individual materials can be found in the products Technical Information.

The SinoJect System

REF	Name	MR status
7303	SinoJect Instrument	MR-Unsafe
7305	SinoJect Rods Set	MR-Unsafe

Following products in the SinoJect System, supplied by Atos Medical AB are electrically nonconductive, nonmetallic, and nonmagnetic and have therefore no potential for interaction with the MR field. They are solely manufactured by plastic material and silicone rubber and therefore the devices are considered to be **MR-safe**, as defined in ASTM F2503. The individual materials can be found in the products Technical Information.

The SinoJect System

REF	Name	MR status
7302	SinoJect Staytube, Catheter for Puncture	MR-Safe
7300	SinoJect Lavage Tube, Female Cone Connection	MR-Safe
7304	SinoJect Lavage Tube, Luer Cone Connection	MR-Safe

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MR-Safety information TheraBite Jaw Motion Rehabilitation System

The TheraBite Jaw Motion Rehabilitation System, supplied by Atos Medical AB are considered to be **MR-Unsafe**, since they contain metallic components that have potential of interfering with the MR-field. Since the Bite Pads, Range of motion scale and ActiveBand Kit is part of the TheraBite Jaw Motion Rehabilitation System and is only used when utilizing a TheraBite these products are also considered to be MR-Unsafe. The individual materials can be found in the products Technical Information.

The TheraBite Jaw Motion Rehabilitation System

REF	Name	MR Status
TH001	TheraBite Jaw Motion Rehabilitation System, Adult	MR-Unsafe
TH002	TheraBite Jaw Motion Rehabilitation System, Pediatric	MR-Unsafe
PA001	TheraBite Bite Pad, Regular	MR-Unsafe
PA002	TheraBite Bite Pad, Edentulous	MR-Unsafe
PA003	TheraBite Bite Pad, Pediatric	MR-Unsafe
SC001	TheraBite Range of Motion Scale	MR-Unsafe
8260	TheraBite ActiveBand Kit	MR-Unsafe

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MR-Safety information TympoVent Otologic Ventilation Tubes

Following products of the TympoVent Otologic Ventilation Tubes, supplied by Atos Medical AB are electrically nonconductive, nonmetallic, and nonmagnetic and have therefore no potential for interaction with the MR field. They are solely manufactured by plastic material and silicone rubber and therefore the devices are considered to be **MR-safe**, as defined in ASTM F2503. The individual materials can be found in the products Technical Information.

The TympoVent Otologic Ventilation Tubes

REF	Name	MR status
7031, 7037	Donaldson type	MR-Safe
7013	Bevel Bobbin type	MR-Safe
7020, 7030, 7021	Shepard type	MR-Safe
7003, 7010, 7012	Straight tube	MR-Safe
7038, 7029, 7034	Armstrong type	MR-Safe
7014-W	Reuter Bobbin type	MR-Safe
7024	Reuter Bobbin type	MR-Safe
7016	Collar Button type	MR-Safe
7018	Star Tube	MR-Safe
7039	Paparella with Tab (ID 1,1mm)	MR-Safe
7000, 7001, 7002	T-tube	MR-Safe

Following products of the TympoVent Otologic Ventilation Tubes, supplied by Atos Medical AB are considered to be **MR-Unsafe**, since they contain metallic components that have potential of interfering with the MR-field. The individual materials can be found in the products Technical Information.

The TympoVent Otologic Ventilation Tubes

REF	Name	MR status
7043, 7044, 7045, 7046	Tübingen type – Gold	MR-Unsafe
7017	Tübingen type – Titanium	MR-Unsafe

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