

## Technical Info / Material Data Sheet

Document ID: PF048-01-TechInfo	Edition: 04
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<b>REF Number</b>	7000, 7001, 7002
<b>Product Name</b>	T-tube
<b>Models:</b>	3 lengths; 6.0 mm, 7.5 mm and 12.0 mm
<b>Classification:</b> (MDD 93/42/EEC)	IIb (2.4 Rule 8)
<b>CE Mark:</b>	Yes
<b>GMDN code:</b>	33794 (Tympanostomy tube)
<b>Produced by:</b>	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
<b>Intended Use:</b>	<p>TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.</p> <p>Pathologic conditions where ventilation tubes are indicated include for example:</p> <ul style="list-style-type: none"> <li>- Secretory otitis media with effusion</li> <li>- Recurrent acute otitis media not responding satisfactory to conventional therapy</li> </ul>
<b>Description:</b>	TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.
<b>Sterilization:</b>	EO-sterilization.
<b>Raw material:</b>	Silicone
<b>Latex information</b>	Not manufactured with natural rubber latex.
<b>Biological origin:</b>	The device is not manufactured with any materials derived from human or animal source.
<b>Handling and storage:</b>	Keep dry and away from sunlight. Temperature limit 2-42°C.
<b>Waste handling and disposal:</b>	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
<b>Hazardous components:</b>	None.
<b>Expiration date:</b>	5 years after manufacturing.

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Edition: 04 Release date: 2016-04-06

Document No.: 1000019017

Released



Atos Medical Your voice

# Technical Info / Material Data Sheet

**Packaging:** TympoVent is single-packed in a box of polypropylene (PP) and then packed in a blister-package made of PETG film and a Tyvek (spun-bounded polyethylene) topfilm. It is then packed in a cardboard box containing 10 pieces and Instructions for use.

**Reviewed by:**

Vice President QA&RA

2016-03-18

Date

**Approved by:**

Vice President Design & Development

2016-03-30

Date

Edition: 04 Release date: 2016-04-06

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## Technical Info / Material Data Sheet

Document ID: PF048-02-TechInfo

Edition: 04

<b>REF Number</b>	7003, 7010, 7012
<b>Product Name</b>	Straight Tube
<b>Models:</b>	3 models; Outer diameter 2.2 mm, 2.4 mm and 2.7 mm
<b>Classification:</b> (MDD 93/42/EEC)	Iib (2.4 Rule 8)
<b>CE Mark:</b>	Yes
<b>GMDN code:</b>	33794 (Tympanostomy tube)
<b>Produced by:</b>	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
<b>Intended Use:</b>	<p>TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.</p> <p>Pathologic conditions where ventilation tubes are indicated include for example:</p> <ul style="list-style-type: none"> <li>- Secretory otitis media with effusion</li> <li>- Recurrent acute otitis media not responding satisfactory to conventional therapy</li> </ul>
<b>Description:</b>	TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.
<b>Sterilization:</b>	EO-sterilization.
<b>Raw material:</b>	Polytetrafluoroethylene (PTFE)
<b>Latex information</b>	Not manufactured with natural rubber latex.
<b>Biological origin:</b>	The device is not manufactured with any materials derived from human or animal source.
<b>Handling and storage:</b>	Keep dry and away from sunlight. Temperature limit 2-42°C.
<b>Waste handling and disposal:</b>	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
<b>Hazardous components:</b>	None.
<b>Expiration date:</b>	5 years after manufacturing.

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# Technical Info / Material Data Sheet

**Packaging:** TympoVent is single-packed in a box of polypropylene (PP) and then packed in a blister-package made of PETG film and a Tyvek (spun-bounded polyethylene) topfilm. It is then packed in a cardboard box containing 10 pieces and Instructions for use.

**Reviewed by:**

.....  
Vice President QA&RA

.....  
Date

2016-03-18

**Approved by:**

.....  
Vice President Design & Development

.....  
Date

2016-03-30

Release date: 2016-04-06  
Edition: 04

Document No: 10000019006

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## Technical Info / Material Data Sheet

Document ID: PF048-03-TechInfo

Edition: 04

**REF Number** 7013**Product Name** Bevel Bobbin**Models:** 1 model**Classification:** IIb (2.4 Rule 8)  
(MDD 93/42/EEC)**CE Mark:** Yes**GMDN code:** 33794 (Tympanostomy tube)**Produced by:** Atos Medical AB  
Kraftgatan 8  
P.O. Box 183  
242 22 Hörby  
Sweden**Intended Use:** TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.

Pathologic conditions where ventilation tubes are indicated include for example:

- Secretory otitis media with effusion
- Recurrent acute otitis media not responding satisfactory to conventional therapy

**Description:** TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.**Sterilization:** EO-sterilization.**Raw material:** Polytetrafluoroethylene (PTFE)**Latex information** Not manufactured with natural rubber latex.**Biological origin:** The device is not manufactured with any materials derived from human or animal source.**Handling and storage:** Keep dry and away from sunlight. Temperature limit 2-42°C.**Waste handling and disposal:** Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.**Hazardous components:** None.**Expiration date:** 5 years after manufacturing.

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Document No: 1000018989

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### Technical Info / Material Data Sheet

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**Reviewed by:**

*[Signature]*

Vice President QA&RA

*2016-03-18*

Date

**Approved by:**

*[Signature]*

Vice President Design & Development

*2016-03-30*

Date

Edition: 04 Release date: 2016-04-06

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Released

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## Technical Info / Material Data Sheet

Document ID: PF048-04-TechInfo	Edition: 04
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<b>REF Number</b>	7014-W, 7024
<b>Product Name</b>	Reuter Bobbin
<b>Models:</b>	2 models; Flange outer diameter 2.5 mm and 2.7 mm
<b>Classification:</b> (MDD 93/42/EEC)	IIb (2.4 Rule 8)
<b>CE Mark:</b>	Yes
<b>GMDN code:</b>	33794 (Tympanostomy tube)
<b>Produced by:</b>	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
<b>Intended Use:</b>	<p>TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.</p> <p>Pathologic conditions where ventilation tubes are indicated include for example:</p> <ul style="list-style-type: none"> <li>- Secretory otitis media with effusion</li> <li>- Recurrent acute otitis media not responding satisfactory to conventional therapy</li> </ul>
<b>Description:</b>	TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.
<b>Sterilization:</b>	EO-sterilization.
<b>Raw material:</b>	Polytetrafluoroethylene (PTFE)
<b>Latex information</b>	Not manufactured with natural rubber latex.
<b>Biological origin:</b>	The device is not manufactured with any materials derived from human or animal source.
<b>Handling and storage:</b>	Keep dry and away from sunlight. Temperature limit 2-42°C.
<b>Waste handling and disposal:</b>	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
<b>Hazardous components:</b>	None.
<b>Expiration date:</b>	5 years after manufacturing.

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### Technical Info / Material Data Sheet

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**Reviewed by:**

Vice President QA&RA

2016-03-18

Date

**Approved by:**

Vice President Design & Development

2016-03-30

Date

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## Technical Info / Material Data Sheet

Document ID: PF048-05-TechInfo

Edition: 04

<b>REF Number</b>	7016
<b>Product Name</b>	Collar Button
<b>Models:</b>	1 model
<b>Classification:</b> (MDD 93/42/EEC)	IIb (2.4 Rule 8)
<b>CE Mark:</b>	Yes
<b>GMDN code:</b>	33794 (Tympanostomy tube)
<b>Produced by:</b>	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
<b>Intended Use:</b>	<p>TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.</p> <p>Pathologic conditions where ventilation tubes are indicated include for example:</p> <ul style="list-style-type: none"> <li>- Secretory otitis media with effusion</li> <li>- Recurrent acute otitis media not responding satisfactory to conventional therapy</li> </ul>
<b>Description:</b>	TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.
<b>Sterilization:</b>	EO-sterilization.
<b>Raw material:</b>	Polytetrafluoroethylene (PTFE)
<b>Latex information</b>	Not manufactured with natural rubber latex.
<b>Biological origin:</b>	The device is not manufactured with any materials derived from human or animal source.
<b>Handling and storage:</b>	Keep dry and away from sunlight. Temperature limit 2-42°C.
<b>Waste handling and disposal:</b>	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
<b>Hazardous components:</b>	None.
<b>Expiration date:</b>	5 years after manufacturing.

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**Reviewed by:**

*[Handwritten signature]*

Vice President QA&RA

*2016-03-18*

Date

**Approved by:**

*[Handwritten signature]*

Vice President Design & Development

*2016-03-30*

Date

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## Technical Info / Material Data Sheet

Document ID: PF048-06-TechInfo	Edition: 04
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<b>REF Number</b>	7018
<b>Product Name</b>	Star Tube
<b>Models:</b>	1 model
<b>Classification:</b> (MDD 93/42/EEC)	IIb (2.4 Rule 8)
<b>CE Mark:</b>	Yes
<b>GMDN code:</b>	33794 (Tympanostomy tube)
<b>Produced by:</b>	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
<b>Intended Use:</b>	<p>TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.</p> <p>Pathologic conditions where ventilation tubes are indicated include for example:</p> <ul style="list-style-type: none"> <li>- Secretory otitis media with effusion</li> <li>- Recurrent acute otitis media not responding satisfactory to conventional therapy</li> </ul>
<b>Description:</b>	TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.
<b>Sterilization:</b>	EO-sterilization.
<b>Raw material:</b>	Silicone
<b>Latex information</b>	Not manufactured with natural rubber latex.
<b>Biological origin:</b>	The device is not manufactured with any materials derived from human or animal source.
<b>Handling and storage:</b>	Keep dry and away from sunlight. Temperature limit 2-42°C.
<b>Waste handling and disposal:</b>	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
<b>Hazardous components:</b>	None.
<b>Expiration date:</b>	5 years after manufacturing.

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# Technical Info / Material Data Sheet

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**Reviewed by:**

Vice President QA&RA

2016-03-18

Date

**Approved by:**

Vice President Design & Development

2016-03-30

Date

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## Technical Info / Material Data Sheet

Document ID: PF048-07-TechInfo	Edition: 05
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<b>REF Number</b>	7020, 7021, 7030
<b>Product Name</b>	Shepard
<b>Models:</b>	3 models; with tail (7020, 7021) and without tail (7030)
<b>Classification:</b> (MDD 93/42/EEC)	IIb (2.4 Rule 8)
<b>CE Mark:</b>	Yes
<b>GMDN code:</b>	33794 (Tympanostomy tube)
<b>Produced by:</b>	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
<b>Intended Use:</b>	<p>TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.</p> <p>Pathologic conditions where ventilation tubes are indicated include for example:</p> <ul style="list-style-type: none"> <li>- Secretory otitis media with effusion</li> <li>- Recurrent acute otitis media not responding satisfactory to conventional therapy</li> </ul>
<b>Description:</b>	TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.
<b>Sterilization:</b>	EO-sterilization.
<b>Raw material:</b>	Fluoropolymer PVdF Kynar precoloured with the blue pigment Phtalocyanin blue.
<b>Latex information</b>	Not manufactured with natural rubber latex.
<b>Biological origin:</b>	The device is not manufactured with any materials derived from human or animal source.
<b>Handling and storage:</b>	Keep dry and away from sunlight. Temperature limit 2-42°C.
<b>Waste handling and disposal:</b>	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
<b>Hazardous components:</b>	None.
<b>Expiration date:</b>	5 years after manufacturing.

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Atos Medical Your voice

# Technical Info / Material Data Sheet

**Packaging:** TympoVent is single-packed in a box of polypropylene (PP) and then packed in a blister-package made of PETG film and a Tyvek (spun-bounded polyethylene) topfilm. It is then packed in a cardboard box containing 10 pieces and Instructions for use.

**Reviewed by:**

Vice President QA&RA

2016-03-18

Date

**Approved by:**

Vice President Design & Development

2016-03-30

Date

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Quality Management System

Page No. 1 of 2

**Technical Info / Material Data Sheet**

Document ID: PF048-08-TechInfo

Edition: 04

**REF Number** 7029, 7034, 7038**Product Name** Armstrong**Models:** 3 models; Bevel Grommet (7038, 7029) and Plain end (7034)**Classification:** IIb (2.4 Rule 8)  
(MDD 93/42/EEC)**CE Mark:** Yes**GMDN code:** 33794 (Tympanostomy tube)**Produced by:** Atos Medical AB  
Kraftgatan 8  
P.O. Box 183  
242 22 Hörby  
Sweden**Intended Use:** TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.Pathologic conditions where ventilation tubes are indicated include for example:  
- Secretory otitis media with effusion  
- Recurrent acute otitis media not responding satisfactory to conventional therapy**Description:** TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.**Sterilization:** EO-sterilization.**Raw material:** Silicone (7029, 7034), Polyvinylidene fluoride (PVDF) (7038)**Latex information** Not manufactured with natural rubber latex.**Biological origin:** The device is not manufactured with any materials derived from human or animal source.**Handling and storage:** Keep dry and away from sunlight. Temperature limit 2-42°C.**Waste handling and disposal:** Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.**Hazardous components:** None.**Expiration date:** 5 years after manufacturing.

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# Technical Info / Material Data Sheet

**Packaging:** TympoVent is single-packed in a box of polypropylene (PP) and then packed in a blister-package made of PETG film and a Tyvek (spun-bounded polyethylene) topfilm. It is then packed in a cardboard box containing 10 pieces and Instructions for use.

**Reviewed by:**

Vice President QA&RA

2016-03-18

Date

**Approved by:**

Vice President Design & Development

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## Technical Info / Material Data Sheet

Document ID: PF048-09-TechInfo	Edition: 04
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<b>REF Number</b>	7031, 7037
<b>Product Name</b>	Donaldson
<b>Models:</b>	2 models; in silicone (7031) and in PTFE (7037)
<b>Classification:</b> (MDD 93/42/EEC)	IIb (2.4 Rule 8)
<b>CE Mark:</b>	Yes
<b>GMDN code:</b>	33794 (Tympanostomy tube)
<b>Produced by:</b>	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
<b>Intended Use:</b>	<p>TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.</p> <p>Pathologic conditions where ventilation tubes are indicated include for example:</p> <ul style="list-style-type: none"> <li>- Secretory otitis media with effusion</li> <li>- Recurrent acute otitis media not responding satisfactory to conventional therapy</li> </ul>
<b>Description:</b>	TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.
<b>Sterilization:</b>	EO-sterilization.
<b>Raw material:</b>	Silicone (7031) and Polytetrafluoroethylene (PTFE) (7037)
<b>Latex information</b>	Not manufactured with natural rubber latex.
<b>Biological origin:</b>	The device is not manufactured with any materials derived from human or animal source.
<b>Handling and storage:</b>	Keep dry and away from sunlight. Temperature limit 2-42°C.
<b>Waste handling and disposal:</b>	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
<b>Hazardous components:</b>	None.
<b>Expiration date:</b>	5 years after manufacturing.

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Document No.: QMC-730-115-en Issue No.: 06 Valid from: 2014-12-12 Time stamp: 2016-03-16 13:40 File name: PF048-09-TechInfo

Edition: 04 Release date: 2016-04-06

Document No.: 1000018988

Released



Atos Medical Your voice

# Technical Info / Material Data Sheet

**Packaging:** TympoVent is single-packed in a box of polypropylene (PP) and then packed in a blister-package made of PETG film and a Tyvek (spun-bounded polyethylene) topfilm. It is then packed in a cardboard box containing 10 pieces and Instructions for use.

**Reviewed by:**

Vice President QA&RA

2016-03-18

Date

**Approved by:**

Vice President Design & Development

2016-03-30

Date

Edition: 04 Release date: 2016-04-06

Document No: 1000018988

Released

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Document No.: QMC-730-115-en Issue No.: 06 Valid from: 2014-12-12 Time stamp: 2016-03-16 13:40 File name: PF048-09-TechInfo

## Technical Info / Material Data Sheet

Document ID: PF048-10-TechInfo	Edition: 05
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<b>REF Number</b>	7039
<b>Product Name</b>	Paparella with Tab (ID 1.1mm)
<b>Models:</b>	1 model.
<b>Classification:</b> (MDD 93/42/EEC)	IIb (2.4 Rule 8)
<b>CE Mark:</b>	Yes
<b>GMDN code:</b>	33794 (Tympanostomy tube)
<b>Produced by:</b>	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
<b>Intended Use:</b>	<p>TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.</p> <p>Pathologic conditions where ventilation tubes are indicated include for example:</p> <ul style="list-style-type: none"> <li>- Secretory otitis media with effusion</li> <li>- Recurrent acute otitis media not responding satisfactory to conventional therapy</li> </ul>
<b>Description:</b>	TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.
<b>Sterilization:</b>	EO-sterilization.
<b>Raw material:</b>	Silicone
<b>Latex information</b>	Not manufactured with natural rubber latex.
<b>Biological origin:</b>	The device is not manufactured with any materials derived from human or animal source.
<b>Handling and storage:</b>	Keep dry and away from sunlight. Temperature limit 2-42°C.
<b>Waste handling and disposal:</b>	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
<b>Hazardous components:</b>	None.
<b>Expiration date:</b>	5 years after manufacturing.

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Edition: 05 Release date: 2016-04-06

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Released



Atos Medical Your voice

### Technical Info / Material Data Sheet

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**Reviewed by:**

Vice President QA&RA

2016-03-18

Date

**Approved by:**

Vice President Design & Development

2016-03-30

Date

Edition: 05 Release date: 2016-04-06

Document No: 10000019013

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## Technical Info / Material Data Sheet

Document ID: PF048-11-TechInfo

Edition: 05

<b>REF Number</b>	7017, 7043, 7044, 7045, 7046
<b>Product Name</b>	TympoVent Tübingen
<b>Models:</b>	5 models; 2 inner diameters; 1.25 mm or 1.5 mm, with or without wire.
<b>Classification:</b> (MDD 93/42/EEC)	IIb (2.4 Rule 8)
<b>CE Mark:</b>	Yes
<b>GMDN code:</b>	33794 (Tympanostomy tube)
<b>Produced by:</b>	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
<b>Intended Use:</b>	<p>TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.</p> <p>Pathologic conditions where ventilation tubes are indicated include for example:</p> <ul style="list-style-type: none"> <li>- Secretory otitis media with effusion</li> <li>- Recurrent acute otitis media not responding satisfactory to conventional therapy</li> </ul>
<b>Description:</b>	TympoVent ventilation (tympanostomy) tubes are small tubular implants, which are placed through an incision made in the tympanic membrane in order to connect the middle ear cavity with the external auditory canal. They are used for temporary ventilation of the middle ear and/or for drainage of fluids from the middle ear into the external auditory canal.
<b>Sterilization:</b>	EO-sterilization.
<b>Raw material:</b>	Titanium (7017) or Glided Silver (7043-7046), Wire (if applicable): Stainless steel.
<b>Latex information</b>	Not manufactured with natural rubber latex.
<b>Biological origin:</b>	The device is not manufactured with any materials derived from human or animal source.
<b>Handling and storage:</b>	Keep dry and away from sunlight. Temperature limit 2-42°C.
<b>Waste handling and disposal:</b>	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
<b>Hazardous components:</b>	None.
<b>Expiration date:</b>	5 years after manufacturing.

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# Technical Info / Material Data Sheet

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**Reviewed by:**

Vice President QA&RA

2016-03-18

Date

**Approved by:**

Vice President Design & Development

2016-03-30

Date

Release date: 2016-04-06  
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