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Technical Info / Material Data Sheet

Document ID: PF048-08-TechInfo	Edition: 04
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REF Number	7029, 7034, 7038
Product Name	Armstrong
Models:	3 models; Bevel Grommet (7038, 7029) and Plain end (7034)
Classification: (MDD 93/42/EEC)	IIb (2.4 Rule 8)
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:	<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"> - 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.

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Technical Info / Material Data Sheet

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REF Number	7013
Product Name	Bevel Bobbin
Models:	1 model
Classification: (MDD 93/42/EEC)	IIb (2.4 Rule 8)
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:	<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"> - 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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Technical Info / Material Data Sheet

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Technical Info / Material Data Sheet

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REF Number	7016
Product Name	Collar Button
Models:	1 model
Classification: (MDD 93/42/EEC)	IIb (2.4 Rule 8)
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:	<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"> - 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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REF Number	7031, 7037
Product Name	Donaldson
Models:	2 models; in silicone (7031) and in PTFE (7037)
Classification: (MDD 93/42/EEC)	IIb (2.4 Rule 8)
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:	<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"> - 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 (7031) and Polytetrafluoroethylene (PTFE) (7037)
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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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.

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Technical Info / Material Data Sheet

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REF Number	7039
Product Name	Paparella with Tab (ID 1.1mm)
Models:	1 model.
Classification: (MDD 93/42/EEC)	IIb (2.4 Rule 8)
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:	<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"> - 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
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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REF Number	7014-W, 7024
Product Name	Reuter Bobbin
Models:	2 models; Flange outer diameter 2.5 mm and 2.7 mm
Classification: (MDD 93/42/EEC)	IIb (2.4 Rule 8)
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:	<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"> - 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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Technical Info / Material Data Sheet

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REF Number	7020, 7021, 7030
Product Name	Shepard
Models:	3 models; with tail (7020, 7021) and without tail (7030)
Classification: (MDD 93/42/EEC)	IIb (2.4 Rule 8)
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:	<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"> - 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:	Fluoropolymer PVdF Kynar precoloured with the blur pigment Phtalocyanin blue.
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.

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Technical Info / Material Data Sheet

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REF Number	7018
Product Name	Star Tube
Models:	1 model
Classification: (MDD 93/42/EEC)	IIb (2.4 Rule 8)
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:	<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"> - 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
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.

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REF Number	7003, 7010, 7012
Product Name	Straight Tube
Models:	3 models; Outer diameter 2.2 mm, 2.4 mm and 2.7 mm
Classification: (MDD 93/42/EEC)	Iib (2.4 Rule 8)
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:	<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"> - 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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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.

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Technical Info / Material Data Sheet

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REF Number	7000, 7001, 7002
Product Name	T-tube
Models:	3 lengths; 6.0 mm, 7.5 mm and 12.0 mm
Classification: (MDD 93/42/EEC)	IIb (2.4 Rule 8)
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:	<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"> - 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
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

Document ID: PF048-11-TechInfo

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REF Number	7017, 7043, 7044, 7045, 7046
Product Name	TympoVent Tübingen
Models:	5 models; 2 inner diameters; 1.25 mm or 1.5 mm, with or without wire.
Classification: (MDD 93/42/EEC)	IIb (2.4 Rule 8)
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:	<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"> - 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:	Titanium (7017) or Glided Silver (7043-7046), Wire (if applicable): Stainless steel.
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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