



April 27, 2018

PRODUCT DATA SHEET

PRODUCT NAME:	AMT G-JET® LOW PROFILE BUTTON G-J TUBE LOW PROFILE GASTRIC AND JEJUNAL BALLOON FEEDING TUBE
ITEM NUMBER SIZE 14FR:	GJ-14XX-XX-I (different sizes from 1,0cmx15cm - until 6,0cmx45cm)
ITEM NUMBER SIZE 16FR:	GJ-16XX-XX-I (different sizes from 1,0cmx15cm – until 6,0cmx45cm)
ITEM NUMBER SIZE 18FR:	GJ-18XX-XX-I (different sizes from 1,2cmx22cm – until 6,0cmx45cm)
INDICATION FOR USE:	The AMT Transgastric-Jejunal feeding tube is indicated for use in patients who cannot absorb adequate nutrition through the stomach, who have intestinal motility problems, gastric outlet obstruction, severe gastroesophageal reflux, are at risk of aspiration, or in those who have had previous esophagectomy or gastrectomy. The use of this tube is also clinically indicated when simultaneous gastric decompression and jejunal feeding are needed. This includes patients in whom malnutrition already exists, or may result, secondary to concurrent conditions
PRODUCT DESCRIPTION:	Equipment to administrate medicines or enteral feeding directly into the stomach and/or jejunum
MATERIAL CONTENTS:	Medical-grade silicone, Medical-grade Silicone tubing with barium Sulfate stripes, Medical-grade Thermoplastic Resin, Medical-grade Silicone Ink, Medical-grade Stainless Steel (for fill valve spring), Medical-grade suture (for the loop at the end), Medical-grade Stainless steel spring (for kink resistance – only for the 16FR and 18FR, not for the 14FR) The softener used in the products is proprietary. It is from the citrate family and is DEHP-free and



Phthalate-free. The glow green material is proprietary, however it has passed all Biocompatibility tests for ISO 10993.

MR:	MR-conditional
STERILE:	Yes
STERILE PROCESS:	EO (Ethylene oxide)
EXPERIATE TIME:	3 years
STORAGE:	Ordinary room temperature
PACKAGING:	AMT does not have PVC in our plastic packaging. The cellulose in the packing is bleached using an ECF process.
BOX MEASURE:	26cmx24cmx5,0cm
CE-MARKING:	CE0413 Medical Device Safety Services GmbH

Dan Filler
Director of Regulatory Affairs



April 27, 2018

PRODUCT DATA SHEET

PRODUCT NAME:	AMT Mini ONE® BALLOON BUTTON LOW PROFILE GASTROSTOMY DEVICE
ITEM NUMBER:	M1-5-XXXX-I (different size from 12FR until 24FR different cm)
ITEM NUMBER SINGLEPACK:	SM1-5-XXXX (different size from 12FR until 24FR different cm)
INDICATION FOR USE:	The Mini ONE® button is designed for a well-established gastrostomy site. The Mini ONE® button has been designed to be a feeding / medication / decompression access into the stomach.
PRODUCT DESCRIPTION:	Equipment to administrate enteral feeding or medicines directly in to the stomach
MATERIAL CONTENTS:	Medical-grade silicone, Medical-grade Silicone Tubing, Medical-grade Thermoplastic Resin, Medical-grade Silicone Ink, The softener used in the products is proprietary. It is from the citrate family and is DEHP-free and Phthalate-free. The glow green material is proprietary, however it has passed all Biocompatibility tests for ISO 10993.
MR:	MR-conditional
STERILE:	Yes
STERILE PROCESS:	EO (Ethylene oxide)
EXPERIATE TIME:	3 years
STORAGE:	Ordinary room temperature
PACKAGING:	AMT does not have PVC in our plastic packaging. The cellulose in the packing is bleached using an ECF process.



BOX MEASURE: Kit 16,5cmx28,0cmx4,0cm Single pack:
14,0cmx17,0cmx3,5cm

CE-MARKING: CE0413 Medical Device Safety Services GmbH

A handwritten signature in black ink that reads "Dan Filler". The signature is written in a cursive style with a horizontal line underneath.

Dan Filler
Director of Regulatory Affairs



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PRODUCT DATA SHEET

PRODUCT NAME:	AMT Mini ONE® CAPSULE NON-BALLOON LOW PROFILE GASTROSTOMY DEVICE
ITEM NUMBER:	M1-2-XXXX (size 14FR, 18FR, 20FR and 24FR different cm)
INDICATION FOR USE:	<p>The Capsule Non-Balloon Button (Pre-Loaded Low Profile Replacement Device) is to be used as a percutaneous replacement gastrostomy tube for a patient with a well-established gastrostomy tract. This device will assist in providing nutrition directly into the stomach through an established stoma in a patient who is unable to consume nutrition by conventional means. The Capsule Non-Balloon Button can also deliver medication and allow for decompression of the stomach.</p>
PRODUCT DESCRIPTION:	Equipment to administrate medicine or enteral feeding directly into the stomach
MATERIAL CONTENTS:	Medical-grade silicone, Medical-grade Thermoplastic Resin, Medical-grade Silicone Ink, Medical-grade Cellulose. The softener used in the products is proprietary. It is from the citrate family and is DEHP-free and Phthalate-free. The glow green material is proprietary, however it has passed all Biocompatibility tests for ISO 10993.
MR:	MR-safe
STERILE:	Yes
STERILE PROCESS:	EO (Ethylene oxide)
EXPERIATE TIME:	3 years
STORAGE:	Ordinary room temperature



PACKAGING: AMT does not have PVC in our plastic packaging.
The cellulose in the packing is bleached using an ECF Process.

BOX MEASURE: 16,5cmx28,0cmx4,0cm

CE-MARKING: CE0413 Medical Device Safety Services GmbH

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Director of Regulatory Affairs



April 27, 2018

PRODUCT DATA SHEET

PRODUCT:	AMT FEEDING SET FOR USE TO THE LOW PROFILE G-JET®, MiniONE® BALLOON BUTTON LOW PROFILE GASTROSTOMY DEVICE, MiniONE® CAPSULE NON-BALLOON BUTTON LOW PROFILE GASTROSTOMY DEVICE
ITEM NUMBER:	6-xxxx-ISOSAF for the G-JET® gastric port different length 8-xxxx-ISOSAF for the G-JET® jejunal port, MiniONE® Balloon and MiniONE® NON BALLOON different length, y-port and bolus
INDICATION FOR USE:	The Mini ONE® Enteral Extension Set is intended for use as an extension set for the Mini ONE® Gastrostomy Button, G-Jet Gastrojejunal Feeding Tube (Jejunal Port), Mic-Key® Secure-Lok® feeding devices, or other compatible enteral feeding devices. The extension set is for administering feeding, medications, and decompression to compatible devices.
PRODUCT DESCRIPTION:	Equipment to administrate medicine or enteral feeding
MATERIAL CONTENTS:	Medical-grade, phthalate-free PVC tubing, Medical-grade Thermoplastic Resins (various), Medical-grade Thermoplastic Ink The softener used in the products is proprietary. It is from the citrate family and is DEHP-free and Phthalate-free.
STERILE:	No
EXPERIATE TIME:	3 years
STORAGE:	Ordinary room temperature
PACKAGING:	AMT does not have PVC in our plastic packaging. The cellulose in the packing is bleached using an ECF process.



BOX MEASURE: 26,0cmx24,0cmx5,5cm

CE-MARKING: CE0413 Medical Device Safety Services GmbH

A handwritten signature in black ink that reads 'Dan Filler'. The signature is written in a cursive style and is positioned above a horizontal line.

Dan Filler
Director of Regulatory Affairs



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PRODUCT DATA SHEET

PRODUCT:	AMT CLAMP
ITEM NUMBER:	4-3000
INDICATION FOR USE:	History of disconnection of feed set from feeding device.
PRODUCT DESCRIPTION:	Equipment used to maintain the connection between the feeding set and the enteral feeding tube.
MATERIAL CONTENTS:	Medical-grade silicone, Medical-grade Silicone Ink.
STERILE:	No
EXPERIATE TIME:	3 years
STORAGE:	Ordinary room temperature
PACKAGING:	AMT does not have PVC in our plastic packaging. The cellulose in the packing is bleached using an ECF process.
BOX MEASURE:	26,0cmx24,0cmx5,5cm
CE-MARKING:	CE0413 Medical Device Safety Services GmbH

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PRODUCT DATA SHEET

PRODUCT:	AMT ENFIT TRANSITION ADAPTERS FOR ENFIT CONNECTIONS
ITEM NUMBER:	TRN 102, TRN 202, TRN 203
INDICATION FOR USE:	<p>The AMT Enteral Transition Adapters are intended to facilitate enteral specific connections between AAMI/CN3(PS) compliant connectors and non ISO 80369-1 compliant legacy enteral connectors</p> <p>Warning: This transition adapter does not protect against inadvertent misconnections with connectors of non-enteral healthcare devices. For enteral use only.</p>
PRODUCT DESCRIPTION:	Equipment used to allow for forward and backward compatibility of administering devices to the feeding set.
MATERIAL CONTENTS:	Medical-grade Thermoplastic Resins (various), Medical-grade Thermoplastic Ink
STERILE:	No
EXPIRATION TIME:	3 years
STORAGE:	Ordinary room temperature
PACKAGING:	AMT does not have PVC in our plastic packaging. The cellulose in the packing is bleached using an ECF process.
BOX MEASURE:	26,0cmx24,0cmx5,5cm
CE-MARKING:	CE0413 Medical Device Safety Services GmbH

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PRODUCT DATA SHEET

PRODUCT:	AMT BALLOON STOMA MEASURING DEVICE
ITEM NUMBER:	1704
INDICATION FOR USE:	The AMT Balloon Stoma Measuring Device is used to assist in determining the length of an existing stoma tract for selecting the proper length replacement feeding tube. Minimum French Size is 10FR. Other applications are not advised.
PRODUCT DESCRIPTION:	Equipment used to measure the stoma length.
MATERIAL CONTENTS:	Medical-grade silicone, Medical-grade Silicone Tubing, Medical-grade Thermoplastic Resins (various), Medical-grade Silicone Ink.
STERILE:	Yes
EXPERIATE TIME:	3 years
STORAGE:	Ordinary room temperature
PACKAGING:	AMT does not have PVC in our plastic packaging. The cellulose in the packing is bleached using an ECF process.
BOX MEASURE:	26,0cmx24,0cmx5,5cm
CE-MARKING:	CE0413 Medical Device Safety Services GmbH

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