

PATIENT INFORMATION danuButton® Gastrostomy Button





Dear patient, relatives and carers,

If you are reading these words, your attending physician is planning enteral nutrition therapy for you or your relative, or you are already receiving enteral nutrition.

This brochure is intended to give you important information and the necessary confidence in using danumed's gastrostomy button, the danuButton[®]. However, if you are still unsure, please contact your attending physician in confidence.

danumed Medizintechnik GmbH is a family-run, innovative, German medical technology company with high quality standards and many years of experience in enteral nutrition. Patient safety is danumed's top priority, which is why we only use high-quality materials for the danuButton® and all components of the danuButton® Sets, which are free of harmful substances and ensure safe use and long product life.

When developing our products, we also pay special attention to patient comfort. We are constantly working to optimize our products so that they are as easy and comfortable to use as possible. A good example of this is the innovative ENSwivel® rotating ring, which makes life much easier for patients and users. Your best possible care is very close to our hearts, and we work on it with full commitment every day.

With best regards, Sonja und Hans Winklmann

The danuButton® Gastrostomy Button

The danuButton® is a replacement feeding tube and can replace a PEG tube, when the gastrostomy has completely healed. A gastric stoma is an artificially created channel between the stomach and the abdominal wall. Usually, this channel is healed after 4 – 6 weeks after the initial insertion, so that a button can replace the tube of the initial insertion. To do this, the button is pushed into the existing gastric stoma from the outside and fixed in the stomach by inflating a silicone balloon with fluid.

The danuButton® is a low-profile tube that is discreet under clothing and hardly restricts freedom of movement.

It is easy to clean and can even be worn while bathing and showering.



▼ The right danuButton® for every patient

The danuButton® is offered in a variety of sizes and lengths so that every patient can be fitted with the exact button they need.

danuButton® – For that extra bit of individuality.

✓ The danuButton® is small, low in profile and discreet

The low-profile design of the outer retaining plate allows the button to be easily hidden under clothing and ensures the best possible freedom of movement in everyday life.

danuButton® - For that extra bit of quality of life.

✓ High-quality materials for safety and comfort

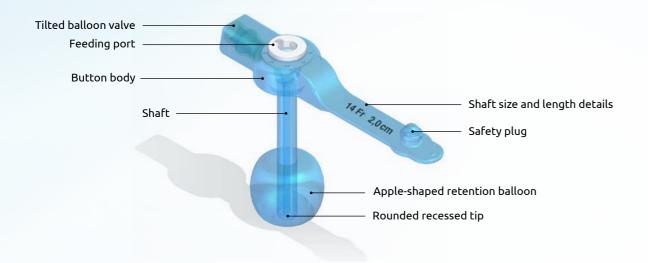
The danuButton® is made from high-quality medical grade silicone which is very soft and flexible for excellent wearing comfort.

The danuButton® and ALL accessories of the danuButton® Sets are latex-free, PVC-free and free of harmful plasticizers such as DEHP or BPA.

danuButton® – For that extra bit of safety.

The initial insertion of a feeding tube or a button is done by a physician. The change of the button can be done either by medical professionals, but also by trained relatives or by trained patients themselves.

danumed patient information danumed patient information



The balloon valve:

- For filling or deflating the balloon when changing the danuButton[®]
- A Luer syringe is connected to the balloon valve and the water for blocking the balloon is then applied into the balloon

The inner retention balloon:

- Serves to securely fix the danuButton® inside the stomach
- Seals the inside of the stomach particularly well due to its apple shape and thus prevents leakage of stomach contents
- With right handling and correct filling, the balloon of the danuButton® is extraordinarily stable and usually allows for a prolonged duration of use

The button body:

- Serves to securely fix the danuButton® to the abdominal wall and prevents the danuButton® from slipping
- Should lie just above the skin to avoid pressure points

The feeding port:

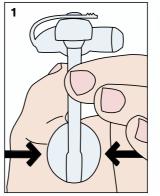
- The feeding port is always closed with the safety plug so that no stomach contents can leak out
- Additional protection is provided by a built-in anti-reflux valve, which prevents the stomach contents from leaking even when the safety closure is opened
- By connecting a danumed® Extension Set to the danuButton®, the anti-reflux valve is opened and tube feeds, liquids or medications can be administered

IMPORTANT: Please note that food, fluids or medication must always be administered via an extension set,

NEVER WITHOUT AN EXTENSION SET!

Brief instructions for placing the danuButton®

Before use, please wash your hands thoroughly, disinfect if necessary and/or wear disposable gloves. A spare danuButton® should always be at hand to prevent the stoma from closing.

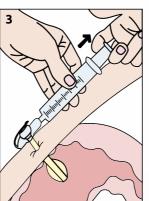


Take the 10 ml Luer syringe from the danuButton® set and fill the balloon with sterile water via the balloon valve.

of the balloon and its symmetry. Remove the water

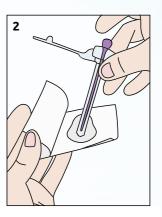
Check the tightness

again.



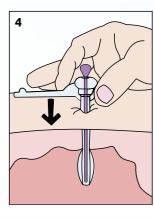
Now connect the 10 ml Luer syringe to the balloon valve of the button that is already in place and remove the water.

Slowly pull the button out of the stoma.

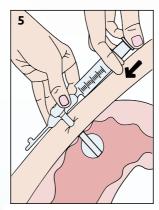


Push the insertion aid completely into the feeding port of the danuButton® (insertion aid can be used optionally).

Apply the enclosed lubricant gel to the gauze pad and moisten the tip of the danuButton® with it to increase lubrication. Do NOT use oil or vaseline.



Now carefully insert the danuButton® into the stoma until it lies flat on the skin and remove the insertion aid, if used.



Hold the danuButton® with one hand and fill the balloon with the recommended amount of water.

Close the button and clean the stoma site with the enclosed gauze pads.

Shaft sizes and filling quantities of the balloon:

\overline{T}	Shaft size in Fr	Balloon volume in ml
EmT	12	3.0
<u>E</u>	14	4.0
− H₂O	16	5.0
E	18	5.0
\neg	20	8.0
u	24	8.0
U	24	8.0

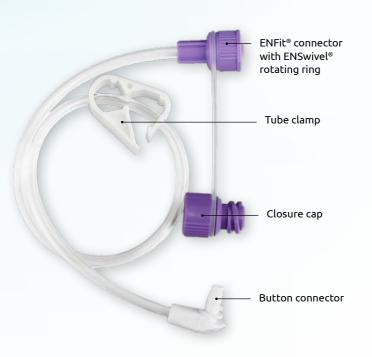
IMPORTANT: NEVER fill the balloon with air! This is because air escapes relatively quickly, which can cause the button to change its position or even fall out prematurely. It is best to fill the balloon only with sterile or distilled water to ensure a long life.

Never use saline solution!

Never fill the balloon with more water than the amount indicated in the table!

The danumed® Extension Set

The extension set is the connecting piece between the danuButton® and usually an enteral syringe for the administration of tube feedings, liquids or medication.



Innovative ENSwivel® rotating ring for easy connection and disconnection of ENFit® connections.

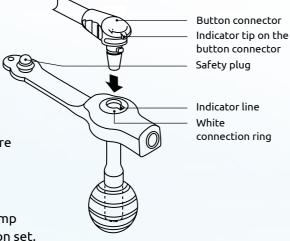


High-quality materials allow for **up to 14 days of use**:

- Button connector and ENFit® connector made of Tritan™ – break-resistant and resistant to aggressive drugs
- Tube made of polyurethane biocompatible, kink-resistant and stays soft (without plasticizers)

Connecting the danumed® Extension Set to the danuButton®

- Wash your hands thoroughly.
 Close the tube clamp on the extension set.
- **2.** Carefully pull the safety plug out of the feeding port of the button.
- 3. Insert the button connector of the extension set into the white feeding port. Align the indicator tip on the button connector of the extension set and the indicator line on the button.
- **4.** Press the button connector down with light pressure and fix it clockwise with a ½ to ¾ turn until a slight resistance is felt. Now the extension set is firmly attached to the button.
- 5. Screw the ENFit® syringe, gravity feeding set or pump feeding set to the ENFit® connector of the extension set. Open the tube clamp and start administering enteral nutrition, fluids and/or medication.



IMPORTANT: Clinicians may advise instructions on the duration of Extension Set use. It is important to note that the danumed® Extension Set can be used for up to 14 days and must be replaced after this period.

Set contents and product codes of the danuButton® Premium Set



The danuButton® Premium Set already contains all components necessary for the replacement of the gastrostomy button. For an easy and comfortable button replacement.

Included in the danuButton® Premium Set:

- danuButton[®] Gastrostomy Button
- danumed® Extension Set for Gastrostomy Button, 30 cm, Bolus-ENFit®, ENSwivel®, straight button connector
- danumed® Extension Set for Gastrostomy Button, 30 cm, Y-ENFit®, ENSwivel®, angled button connector
- danumed® Introducer (insertion aid)
- o danumed® Balloon Syringe 10 ml
- o danumed® Enteral Syringe, Single Use 60 ml, ENFit®
- optiLube Lubricant
- 4 gauze pads

			Product codes	
Fre	nch size	12	14	16
	0.8	DA 1041 1208	DA 1041 1408	DA 1041 1608
	1.0	DA 1041 1210	DA 1041 1410	DA 1041 1610
	1.2	DA 1041 1212	DA 1041 1412	DA 1041 1612
	1.5	DA 1041 1215	DA 1041 1415	DA 1041 1615
	1.7	DA 1041 1217	DA 1041 1417	DA 1041 1617
	2.0	DA 1041 1220	DA 1041 1420	DA 1041 1620
E	2.3	DA 1041 1223	DA 1041 1423	DA 1041 1623
Length (cm)	2.5	DA 1041 1225	DA 1041 1425	DA 1041 1625
gui	2.7	DA 1041 1227	DA 1041 1427	DA 1041 1627
Ľ	3.0	DA 1041 1230	DA 1041 1430	DA 1041 1630
	3.5	DA 1041 1235	DA 1041 1435	DA 1041 1635
	4.0	DA 1041 1240	DA 1041 1440	DA 1041 1640
	4.5	DA 1041 1245	DA 1041 1445	DA 1041 1645
	5.0	DA 1041 1250	DA 1041 1450	DA 1041 1650
	5.5		DA 1041 1455	
	6.0		DA 1041 1460	
	6.5		DA 1041 1465	

	Product codes							
Fre	nch size	18	20	24				
	0.8	DA 1041 1808	DA 1041 2008	DA 1041 2408				
	1.0	DA 1041 1810	DA 1041 2010	DA 1041 2410				
	1.2	DA 1041 1812	DA 1041 2012	DA 1041 2412				
	1.5	DA 1041 1815	DA 1041 2015	DA 1041 2415				
	1.7	DA 1041 1817	DA 1041 2017	DA 1041 2417				
Ê	2.0	DA 1041 1820	DA 1041 2020	DA 1041 2420				
9	2.3	DA 1041 1823	DA 1041 2023	DA 1041 2423				
Length (cm)	2.5	DA 1041 1825	DA 1041 2025	DA 1041 2425				
	2.7	DA 1041 1827	DA 1041 2027	DA 1041 2427				
	3.0	DA 1041 1830	DA 1041 2030	DA 1041 2430				
	3.5	DA 1041 1835	DA 1041 2035	DA 1041 2435				
	4.0	DA 1041 1840	DA 1041 2040	DA 1041 2440				
	4.5	DA 1041 1845	DA 1041 2045	DA 1041 2445				
	5.0	DA 1041 1850	DA 1041 2050	DA 1041 2450				
	6.0	DA 1041 1860						

Daily care and maintenance checklist

For a long life of the danuButton®, it is important to carry out the following care measures daily:

- **Mobility:** To ensure the mobility of the danuButton®, it is best to rotate the Button 360° every day.
- **Stoma assessment:** Check the skin around the stoma for redness, skin irritation, edema and swelling. After feeding, observe whether stomach contents leak out. Always keep the stoma site clean.
- **Cleaning the stoma:** Clean the stoma with warm water and mild soap with circular motions starting from the tube and going outward. Use a soft cloth or cotton swab and always dry the stoma site well.
- Cleaning the button: Clean the button with warm water and mild soap. Make sure the tube is manipulated as little as possible. Air thoroughly and let air dry.
- **Button assessment:** Assess the danuButton® for any potential damage, clogs or abnormal discoloration. Check to ensure the button body is 2–3 mm above the skin.
- Flushing the button: After administering enteral nutrition and/or medication, we recommend
 to rinse both, the button and the extension set, with 20 ml room-temperature water (for adults).
 In neonatal and pediatric patients, flush feeding tubes with the lowest volume necessary to
 clear the tube. Clinician advice should be followed as directed. Never use acidic flushing solutions
 such as fruit juices or carbonated beverages to flush the button!

6



danumed Medizintechnik GmbH

Individual solutions are our standard.

We are a family-run, innovative, German medical technology company with high quality standards, many years of expertise in enteral nutrition and a clear customer focus.

Individual customer requests are met with flexibility and reliability.

Personal, competent, collaborative.

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