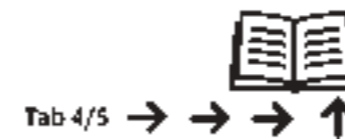


REFs of the procedure pack:

prod		REF	CE
danuButton®	danumed Medizintechnik GmbH Stadtamhof 18 DE-93059 Regensburg GERMANY	DXXYY XX = [FR] YY = [mm]	CE 0044
danumed® Extension Set, 30 cm, Y-ENFit®, ENSwivel®, Button connector right angled	danumed Medizintechnik GmbH Stadtamhof 18 DE-93059 Regensburg GERMANY	DA 1010 3021	CE
danumed® Extension Set, 30 cm, Bolus-ENFit®, ENSwivel®, Button connector straight*	danumed Medizintechnik GmbH Stadtamhof 18 DE-93059 Regensburg GERMANY	DA 1010 3032	CE
danumed® Stiffener (Introducer)	danumed Medizintechnik GmbH Stadtamhof 18 DE-93059 Regensburg GERMANY	Tab 4	CE
danumed® Balloon Syringe 10 ml	danumed Medizintechnik GmbH Stadtamhof 18 DE-93059 Regensburg GERMANY	D0008	CE 0044
danumed® Enteral Syringe 60 ml, ENFit®, female*	danumed Medizintechnik GmbH Stadtamhof 18 DE-93059 Regensburg GERMANY	D0007	CE 0044
optiLube	Optimum Medical Solutions Floor 1, Unit 5 Armley Court, Armley-Road, Leeds, LS12 2LB UNITED KINGDOM	1120	CE 2797
Gauze pads	Wilh. Weisweiler GmbH & Co. KG Eulerstraße 9 D-48155 Münster GERMANY	3996187	CE

Tab 3



Tab 4/5 → → → ↑

REF		REF
D1208 D1210 D1212 D1408 D1410 D1412 D1608 D1610 D1612 D1808 D1810 D1812 D2008 D2010 D2012 D2408 D2410 D2412		D0011
D1215 D1217 D1415 D1417 D1615 D1617 D1815 D1817 D2015 D2017 D2415 D2417		D0012
D1220 D1223 D1420 D1423 D1620 D1623 D1820 D1823 D2020 D2023 D2420 D2423		D0013
D1225 D1227 D1425 D1427 D1625 D1627 D1825 D1827 D2025 D2027 D2425 D2427		D0014
D1230 D1430 D1630 D1830 D2030 D2430		D0015
D1235 D1435 D1635 D1835 D2035 D2435		D0016
D1240 D1440 D1640 D1840 D2040 D2440		D0017
D1245 D1445 D1645 D1845 D2045 D2445		D0018
D1250 D1450 D1650 D1850 D2050 D2450		D0019

Tab 4

Length [mm]	08	10	12	15	17	20	23	25	27	30	35	40	45	50
12	x	x	x	x	x	x	x	x	x	x	x	x	x	x
14	x	x	x	x	x	x	x	x	x	x	x	x	x	x
16	x	x	x	x	x	x	x	x	x	x	x	x	x	x
18	x	x	x	x	x	x	x	x	x	x	x	x	x	x
20	x	x	x	x	x	x	x	x	x	x	x	x	x	x
24	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Tab 5

















danuButton® Premium / Compact Set

LOW PROFILE GASTROSTOMY FEEDING TUBE

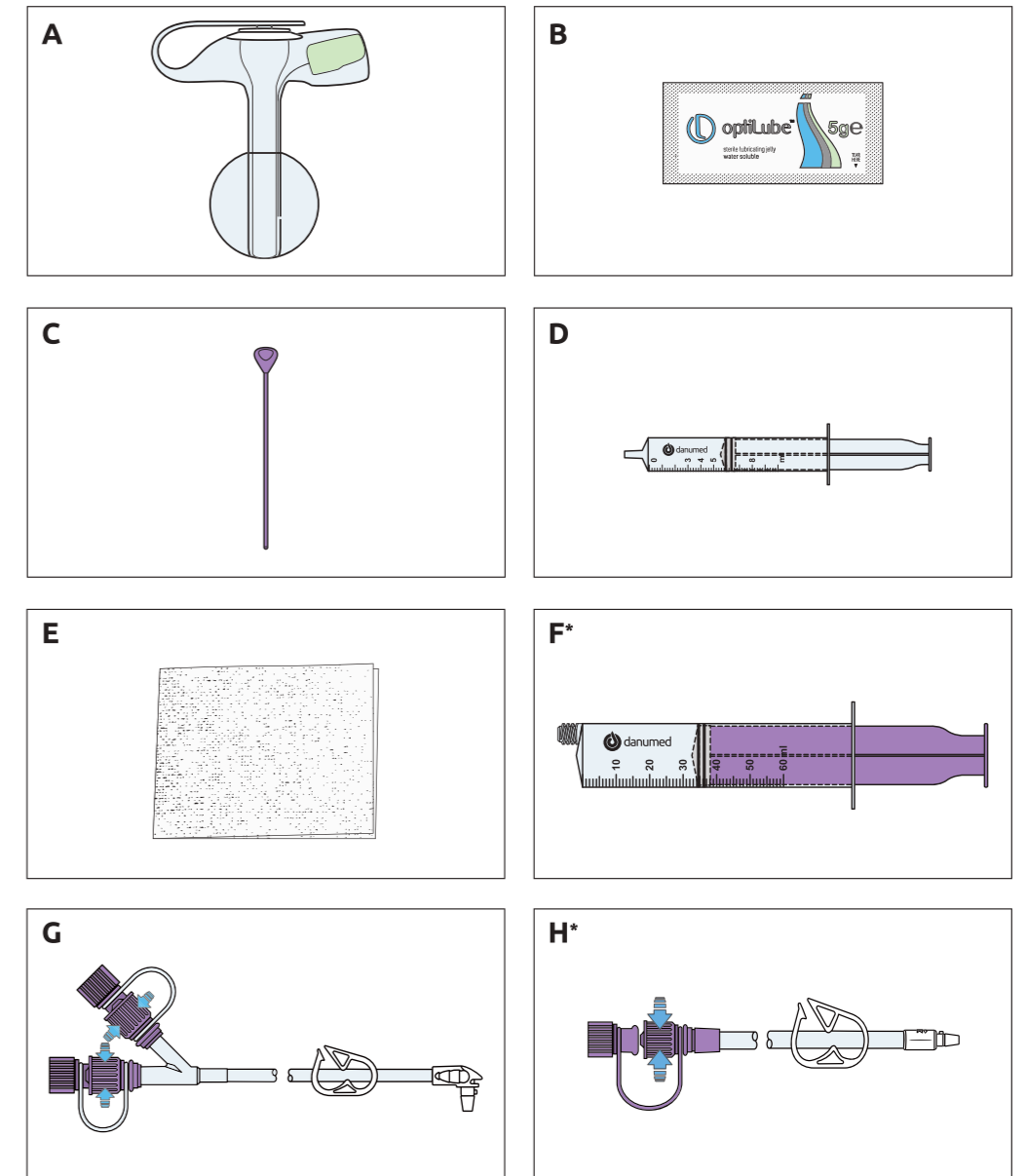
ENFit®  ENSwivel



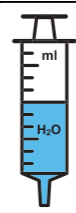
INSTRUCTIONS FOR USE

- | | |
|--|--|
|  danuButton® Gastrostomiesonde, Gebrauchsanweisung |  danuButton® Gastrostomy Button, Gebruiksaanwijzing |
|  دليل الاستعمال زر (Button) فغر المعدة |  danuButton® Gastrostomknapp, Bruksanvisningen |
|  danuButton® Gastrostomi-button, Bruksanvisning |  danuButton® Button gastrostomijnego, Instrukcja obsługi |
|  danuButton® Botón de gastrostomia, Modo de empleo |  danuButton® Button de gastrostomia, Instruções de utilização |
|  danuButton® Gastrostooma-button, Käyttöohjeet |  danuButton® Гастростомический кнопочный интубатор, Инструкция по пользованию |
|  danuButton® Bouton de gastrostomie, Mode d'emploi |  danuButton® Gastrostomi-knapp (button), Bruksanvisning |
|  danuButton® Bottone per gastrostomia, Istruzioni per l'uso |  danuButton® Gastrostomi butonu, Kullanım Talimatları |

07 / 2021, D9002



Tab 1

	Fr/CH	ml
	12	3.0
14	4.0	
16	5.0	
18	5.0	
20	8.0	
24	8.0	

Tab 2



Best Quality made by a German Manufacturer



danumed
MEDIZINTECHNIK

danuButton® Premium / Compact Set

LOW PROFILE GASTROSTOMY FEEDING TUBE

ENFit®



INSTRUCTIONS FOR USE

- | | |
|--|--|
| de danuButton® Gastrostomiesonde, Gebrauchsanweisung | nl danuButton® Gastrostomy Button, Gebruiksaanwijzing |
| ar danuButton® دليل الاستعمال زر (Button) فغر المعدة | no danuButton® Gastrostomiknapp, Bruksanvisningen |
| da danuButton® Gastrostomi-button, Bruksanvisning | pl danuButton® Button gastrostomijnego, Instrukcja obsługi |
| es danuButton® Botón de gastrostomía, Modo de empleo | pt danuButton® Button de gastrostomia, Instruções de utilização |
| fi danuButton® Gastrostooma-button, Käyttöohjeet | ru danuButton® Гастростомический кнопочный интубатор, Инструкция по пользованию |
| fr danuButton® Bouton de gastrostomie, Mode d'emploi | sv danuButton® Gastrostomi-knapp (button), Bruksanvisning |
| it danuButton® Bottone per gastrostomia, Istruzioni per l'uso | tr danuButton® Gastrostomi butonu, Kullanım Talimatları |

CE 0044

STERILE EO



Conformity assessment of the sterilization



of procedure pack:
danumed Medizintechnik GmbH
Stadthof 18
DE-93059 Regensburg
GERMANY

MD



PVC-free



Latex-free



DEHP-free



BPA-free

en

danuButton® Premium Set and Compact Set



Attention!

Read all instructions carefully before use!

The danuButton® is used by trained healthcare professionals or by trained caring relatives or the trained patient themselves.

WARNING NOTICES!!

- This button is only intended for a single use. The product may **NOT be reused or resterilized**. Reuse can pose a potential infection risk and negatively impact reliable functionality. Do not use the product if the packaging is already open or damaged.
- **Check the expiration date!** Do not use the product after this date under any circumstances.
- Do not score, cut, tear, puncture or otherwise **damage** the product **under any circumstances**.
- A single danuButton® can remain in a properly installed and healed stoma for **more than 30 days**, provided there are no complications. If the tube detaches or the hose gets clogged, the patient must immediately contact a physician.



The **usage period** of the danuButton® is impacted by the following factors: Fill volume in the balloon, pH value of the stomach contents and maintaining the balloon.

Replacing the danuButton® after 90 days is recommended.

- A danuButton® as a replacement product should always be ready at home. To prevent the stoma from closing, the button should not be removed until a replacement button is ready.
- **The danuButton® set is only intended for a single patient.**

Set contents

The danuButton® comes in a **Compact Set** and a **Premium Set** with the following components (see Tab 1):

- (A) danuButton® for percutaneous tube feeding and medication administration
- (B) optiLube (5 g) to support button insertion
- (C) danumed® Stiffener (Introducer) to stiffen the button during insertion
- (D) danumed® Balloon Syringe 10 ml to fill the balloon retention system
- (E) gauze pads (4 pieces 10 x 10 cm) to wet the button
- (F) danumed® Enteral Syringe 60 ml, ENFit®, female* for the administration of enteral nutrients and fluids for suction and flushing
- (G) danumed® Extension Set, 30 cm, Y-ENFit®, button connector, angled to connect to the danuButton®
- (H) danumed® Extension Set, 30 cm, Bolus-ENFit®, button connector, straight* to connect to the danuButton®

* only included in the danuButton® Premium Set

Instructions for use OptiLube (B)

COMPOSITION:

Sterile, transparent water-soluble jelly.

• Purified water • Polyethylene Glycol (PEG) • Glycerine • Sodium hydroxide • 4-Hydroxybenzoic acid esters • pH range 5,0 – 7,0

OptiLube is harmless to human tissue.

CONTRAINDICATIONS: Do not use if you have a known sensitivity or allergy to any of the ingredients.

SIDE EFFECTS: There are no known side effects, however, if irritation occurs discontinue using and consult a doctor.

WARNINGS: Do not use if product is damaged or seal is broken. Apply the required amount of lubrication necessary for the procedure. Not for use in the eye.

Description

This danuButton® treatment unit includes a sterile **spare feeding tube made of high-quality medical silicone** for long-term enteral feeding with the necessary accessories (see Tab 3). The button is used as a transition system to directly feed nutrients or medication into the patient's stomach and is available in various sizes and lengths (see Tab 5). The hose size (Fr) and length are indicated on the bracket on each individual danuButton® and on the packaging unit.

Indications

The danuButton® is a **replacement feeding tube** for long-term enteral administration of nutrients and medication directly into the stomach and may not be inserted into the existing and healed stoma for at least 6 weeks after a PEG is inserted. Furthermore, the danuButton® is indicated for patients with a low risk of aspiration and/or require **gastric decompression**.

Contraindications

The danuButton® may **not** be used for patients that do **not have an existing and already healed stoma or a correctly functioning gastrointestinal tract**.

Complications

The following complications can arise when using the danuButton®:

- Infection
- Hypergranulation tissue
- Pressure necrosis¹

¹ If pressure necrosis develops, replace the danuButton® with the next-largest size.

Note: All serious incidents occurring in connection with the devices must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or the patient is established.

Placement of the tube

The danuButton® can be used as a **replacement tube** for an existing tube, using an existing and healed stoma.

Note: After instruction/training by medical professionals, the danuButton® can be exchanged at home by caring relatives or by the patient himself. If there are any uncertainties, problems or complications with the use of the products, the exchange of the button or in the course of the usage duration, a doctor or medical professional should be contacted.

Installing / replacing the danuButton®

Select the correct danuButton® size. Prior to using the treatment unit, do not forget to **thoroughly wash your hands**.

The following numbers refer to the numbers in the figures on the inside of the cover.

(1) Check the danuButton® Compact/Premium Set for damage and open it. **Do not use if the packaging is damaged or already open!**

- (2)** Make sure the danuButton® is functioning properly:
1. Remove the danuButton® from the packaging and check for potential damage.
 2. Fill the retention balloon with the amounts of sterile or distilled water specified in Tab 2 with the help of the included Luer syringe.
 3. Remove the syringe and check for leaks and symmetry by applying slight pressure to the balloon. The balloon symmetry is checked by lightly rolling the balloon between your fingers.
 4. Reinsert the syringe and drain the balloon.

(3) Optionally, the enclosed stiffener (introducer) can be inserted into the feeding port of the danuButton® to give the shaft more stability. Size/color, see Tab 4.

(4) Apply the included lubricant to the included gauze pad.

(5) Wet the tip of the danuButton® with the lubricant on the gauze pad.

(6) Remove the water from the existing gastrostomy button with the help of the included Luer syringe (yellowed due to nutrient administration). In the event another balloon tube is installed (PEG, G-Tube): Remove the tube in accordance with the manufacturer's instructions.

(7) Remove the old gastrostomy button. In the event another balloon tube is installed (PEG, G-Tube): Remove the tube in accordance with the manufacturer's instructions.

(8) Carefully insert the new danuButton® into the stoma and remove the stiffener (introducer) if used in step (3).

(9) Fill the retention balloon with sterile water (required balloon volume, see Tab 2). **Do not use air! Do not use saline solution under any circumstances! Do not inject contrast agents into the balloon!** The tube shaft has its own radiological contrast strips.

Checking the tube position and continuity

1. Connect one of the two included danumed extension sets to the feeding port and connect the included enteral syringe with an ENFit® connection piece with 10ml of water at the proximal end.
2. Aspirate the stomach contents. If stomach contents can be seen in the tube, this confirms that the tube is correctly positioned.
3. Flush the stomach contents out of the tube with water and check the area around the stoma for leaks. If there is a leak, another check must be performed to determine whether the balloon has been correctly filled and whether the correct tube size has been selected.
4. The correct positioning of the tube can also be checked radiologically via the radiopaque strips in the tube shaft.
5. Enteral feeding may only start after ensuring the position is correct and the continuity of the tube.

Connecting the danumed® Extension Set for bolus and continuous feeding

- The included extension sets, if available, may only be used for one patient (single-patient product) and must be replaced after a maximum of 14 days.
- Compatibility: The button connector on this extension set is only compatible with buttons with the following, white connection ring.

Compatibility of the extension set

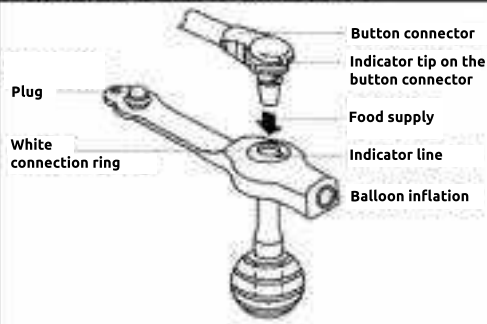
White connection ring in the button



• Connecting

- o Carefully pull the plug on the button out of the feeding port so the non-return valve and white connection ring are visible.
- o Connect the button connector to the button. To this end, place the indicator head on the button connector and the indicator line on the button over each other, slightly press down on the button connector and fixate by turning it clockwise ¼ to ¾ of a turn.

Button and extension set



• Disconnecting:

- o Carefully turn the button connector counter-clockwise until the indicator head on the button connector lines up with the indicator line on the button. Then, carefully pull the button connector out of the button.
- o Close the feeding port on the button with the plug

- **Instructions for use:** If included, thoroughly wash the danumed® Extension Sets with warm water after each use. Remove stuck-on nutrient residues, especially from the connectors, using a soft brush. Let air dry. **Do not resterilize!**

- **Storage:** The products must be stored at room temperature, in a dry environment and in their original packaging. **Avoid direct sunlight and heat.**

danuButton® functions

Information about feeding

Any user feeding and care measures must be based on the current clinical guidelines set forth by the treating hospital/institution!

1. As needed and if included, connect the included bolus-ENFit or Y-ENFit extension set (see Connecting the danumed® Extension Set for bolus and continuous feeding).
2. Set the nutrient solution rate and administration of the nutrient.
3. Flush the extension set and tube with water until the hose is completely transparent. Ensure the water flows easily.
4. Remove the extension set and close the tube (see Connecting the danumed® Extension Set for bolus and continuous feeding).
5. If feeding is continuous, the tube should be flushed with water every 4-6 hours after interrupting the nutrient feed.

Information about medication



Attention!

Prior to administering medications via the danuButton®, always consult a physician!

- The suitability of the medication with respect to grinding them up and interactions with the tube materials must always be clarified with the treating physician and/or pharmacy.
- If possible, only administer fluid medications via the danuButton®.
- Prior to administering medications, check whether the medication is supposed to be administered on an empty or full stomach.
- **Do not** administer oily, sub-lingual or buccal medications, tablets or capsules with delayed release.

- **Never** grind up coated medications as this might result in the improper application of the medication.
- **Never** mix or administer medications with a nutrient solution!
- Thoroughly flush the danuButton® with water before and after administering medications using the extension set.

Decompression

1. Both danumed® Extension Sets, if included, can be used for gastric decompression.
2. Connect the selected extension set to the tube.
3. Drain the stomach contents into the tank.
4. Flush the extension set and the danuButton® with water after performing the decompression.
5. Disconnect the extension set and close the feeding port.

Care and maintenance

To maintain the mobility of the button in the stoma and avoid skin irritations, the button should be rotated **360° every day**.

Guidelines regarding tube continuity

The following instructions regarding proper flushing must be followed to prevent the tube from getting clogged and ensure the continuity of the tube.



Attention!

Always flush through the extension set!

Using a syringe directly at the feeding port may damage the anti-reflux valve and cause a leak.

- The danuButton® should be **replaced regularly** (after 90 days is recommended), to ensure the optimum functionality of the tube. If the button is used for more than 90 days, frequent functional checks are recommended.
- If feeding is continuous, the tube must be flushed every 4 to 6 hours and, when not in use, every 8 hours.
- **Flush the feeding tube before and after every administration of medication** to prevent an interaction between the medication and the nutrient solution which prevents the tube from getting clogged.
- Medications may only be administered separately and the tube must be flushed between administrations of medications. Solid medications must be ground up prior to administration (if the stability and intake of the ingredient permits), diluted and/or dissolved in fresh drinking water.

General flushing instructions

- Use room-temperature tap water to flush the tube. If the quality of the municipal water supply is questionable, sterile water can be used.
- The quantity is based on the patient's age and the treating hospital or institution's clinical guidelines. The patient's hydration status also impacts the flushing quantity. In many cases, an increased flushing volume can prevent the patient from requiring additional fluids intravenously.
- Only the minimum flushing volume should be used for small children and patients with kidney failure in order to maintain the continuity of the tube.

Maintaining the retention balloon

The water volume of the danuButton® must be checked **once a week**.

- Hold the button in one hand and insert the included Luer syringe into the side access port for filling the balloon.
- Remove the water from the balloon and make sure the danuButton® remains in place.
- Compare the removed water quantity with the recommended quantity from **Tab 2**. If the water quantity is

less than the specified quantity, fill the Luer syringe with the required amount of water and fill the balloon with the exact volume. **Only** fill the balloon with **sterile or distilled water**.

- When removing the water, stomach contents may leak out around the tube. Remove it using gauze pads.
- Wait 10-20 minutes and repeat the process to make sure there are no leaks in the balloon. If there is a leak, the button must be replaced in accordance with the instructions.

Daily care and maintenance checklist

1. **Patient assessment**
Examine the patient for pain, pressure and other complaints.
2. **Stoma assessment**
Check the patient for an infection, e.g. redness, skin irritation, edema, swelling, pressure sensitivity, heat, rashes, purulent or gastrointestinal discharge. Examine the patient for signs of pressure necrosis, decubitis or hypergranulation tissue.
3. **Cleaning the stoma**
Clean the stoma with warm water and mild soap with circular motions starting from the tube and going outward.
4. **Button assessment**
Assess the danuButton® for any potential damage, clogs or abnormal discoloration.
5. **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.
6. **Position check**
Check to ensure the proximal end of the button is 2-3 mm above the skin.
7. **Flushing the button**
If feeding is continuous, the button must be flushed every 4 to 6 hours and, when not in use, every 8 hours. Do not use acidic flushing solutions such as fruit juices or carbonated beverages to flush the button. Flush the danuButton® before and after every administration of medications!
8. **Mobility**
To ensure the mobility of the danuButton®, the tube must be rotated 360° every day.

Storage and disposal

The products must be stored out of reach of children, at room temperature and in a dry environment in the original packaging and, after use, immediately disposed of where they are out of reach of children. To this end, comply with the relevant, in-house and public regulations. Avoid direct sunlight and heat.