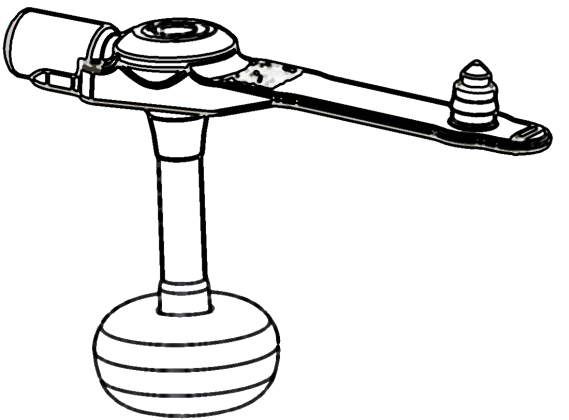
MiniSPC™ Button

Low Profile Suprapubic Catheter



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2 STERILIZE

PHT DEHP

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STERILE EO

Rx Only

C4987-A 12/2024

Made in the U.S.A.

ENGLISH

MiniSPC™ Button

Low-Profile Suprapubic Catheter

INSTRUCTIONS FOR USE

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. ***Notice:*** *Peel off ID sticker from tray and store for future use in patient chart or other convenient location.* The device is provided STERILE for single use. Please inspect all contents of the kit for damage. If damaged, do not use.

INDICATIONS FOR USE

For patients 7 years of age and older with lower urinary tract dysfunctions such as neurogenic bladder dysfunction, congenital malformation or urethral obstruction, or who are severely disabled or requiring constant care. The MiniSPC™ Button & Drainage Set is indicated to be used for temporary suprapubic urinary diversion and drainage for less than or equal to four weeks. The MiniSPC™ Button is intended to be placed directly into the bladder through a secured (initial placement) or formed (replacement) stoma.

CONTRAINDICATIONS

Contraindications for use of the MiniSPC™ Button & Drainage Set include but are not limited to: Carcinoma of the bladder • Ongoing urinary tract infection, except when, in the judgement of the physician, the benefits of suprapubic drainage outweigh the risks • Presence of subcutaneous vascular graft in the suprapubic area

COMPLICATIONS

Potential complications when using the MiniSPC™ Button & Drainage Set include but are not limited to: Incorrect location at insertion, resulting in trauma to the surrounding tissue • Mild burning at insertion site • Blood in urine • Cystitis, urosepsis • Blocked catheter • Development of bladder stomas • Insertion site infection • Peristomal pain • Abscess, wound infection and skin breakdown • Pressure necrosis • Hypergranulation tissue • Intraperitoneal leakage • Buried bumper syndrome • Peristomal leakage • Balloon failure or dislodgement

WARNING: THIS DEVICE IS INTENDED FOR SINGLE USE. DO NOT REUSE, REPROCESS OR RE-STERILIZE THIS MEDICAL DEVICE. DOING SO MAY COMPROMISE BIOCOMPATIBILITY CHARACTERISTICS, DEVICE PERFORMANCE AND/OR MATERIAL INTEGRITY; ANY OF WHICH MAY RESULT IN POTENTIAL PATIENT INJURY, ILLNESS AND/OR DEATH.

KIT CONTENTS

(1) MiniSPC™ Button (Fig. A)
(2) 4 x 4 inch Gauze
(1) Introducer/Stiffener
(1) Water Soluble Lubricant
(1) Luer-Slip Syringe
(1) 12” or 24” Right Angle Drainage Set (Fig. B)

Optional Accessories for Device Placement (Not Included): Dilators, Stoma Measuring Device, Introducer Needle, Scalpel, Guidewire.

Additional Components for Use (Not Included): Replacement Drainage Sets, Drainage Bag

Figure A: MiniSPC™ Button

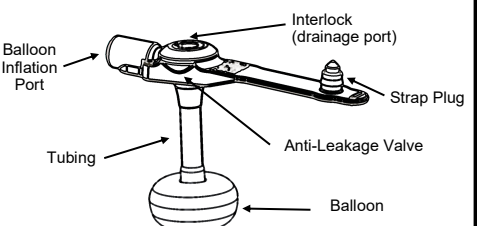


Figure B: Drainage Set

Figure C: Balloon Inflation Port

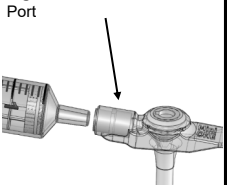
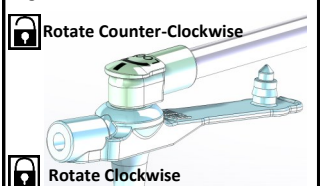


Figure D: Interlock Connection



TYPE OF USAGE – INITIAL PLACEMENT VS REPLACEMENT

The MiniSPC™ Button may be placed either during an initial placement procedure or as a replacement device.

PERFORMING AN INITIAL PLACEMENT

If the patient does not currently have a stoma tract for placement of the MiniSPC™ Button, a new stoma tract will need to be created. This process can only be completed by a healthcare professional per proper cystostomy/vesicostomy surgical procedures. Follow the instructions below starting with the **SUGGESTED INITIAL PLACEMENT PROCEDURES** section.

REPLACING A DEVICE IN AN ESTABLISHED STOMA SITE

If it is determined that a device placed in an existing stoma needs replaced (due to non-optimal functionality or as a pro-active replacement), the current device can be removed from the stoma and the new device can be inserted in the same stoma site. If performing a device replacement, skip straight to the **DEVICE PLACEMENT PROCEDURE** section for the proper method of placing the new device.

NOTE: Device replacement can be performed by the healthcare professional or at home by the patient/caregiver. Do not attempt to replace the device until first discussing the procedure with your healthcare professional.

CAUTION: Selection of the correct size device is critical for safety and comfort of the patient. An inappropriately sized device can cause necrosis, buried bumper syndrome and/or hypergranulation tissue. If patient size/weight has changed since the device was placed, fit is too tight or too loose, or it has been over six months since the stoma was last measured, it is recommended that the stoma is measured to ensure that device size does not need changed.

SUGGESTED INITIAL PLACEMENT PROCEDURES

WARNING: THE MINISPC™ BUTTON SHOULD ONLY BE INITIALLY PLACED BY OR UNDER THE SUPERVISION OF PERSONNEL TRAINED IN PROPER CYSTOSTOMY/VESICOSTOMY SURGICAL PROCEDURES. A THOROUGH UNDERSTANDING OF THE TECHNICAL PRINCIPLES, CLINICAL APPLICATIONS, AND RISKS ASSOCIATED WITH TUBE PLACEMENT IS RECOMMENDED PRIOR TO USING THIS DEVICE.

Initial placement of the MiniSPC™ Button may be performed using an open or percutaneous approach. Studies have suggested that better continence results have been achieved through the endoscopic placement technique.

Option A: Open Approach

1. If the bladder is not already distended, fill the bladder with sterile saline solution.
2. Identify the placement site.
3. Perform vesicostomy according to standard hospital procedure.
4. Measure the stoma length by following the **MEASURE THE STOMA LENGTH** section.
5. Select the correct MiniSPC™ Button size and place the device following the **DEVICE PLACEMENT PROCEDURE.**

Option B: Percutaneous Approach

1. If the bladder is not already distended, fill the bladder with sterile saline solution.
2. Identify the puncture site.
3. Anesthetize the puncture site with local injection of 1% lidocaine.
4. Insert a .038" compatible introducer needle at the puncture site. Advance the introducer needle into the bladder.

WARNING: TAKE CARE NOT TO ADVANCE THE INTRODUCER NEEDLE TOO DEEPLY IN ORDER TO AVOID PUNCTURING THE POSTERIOR BLADDER WALL.

5. Spontaneous return of urine should occur. If bladder pressure is low and urine fails to flow spontaneously through the introducer needle, aspirate to ascertain whether the introducer needle is within the bladder. Placement into the bladder is confirmed after urine is observed.

NOTE: Do not attempt insertion if bladder cannot be located.

6. Once the introducer needle placement in the bladder is confirmed, advance a guidewire through the introducer needle into the bladder.
7. Once the guidewire is in place, remove the introducer needle.
8. Using a #11 blade, make a skin puncture at the midline of the guidewire exit.
9. Advance a dilator over the guidewire and dilate the stoma tract to the desired size.
10. Remove the dilator over the guidewire, leaving the guidewire in place.

CAUTION: Avoid excessive dilation of stoma tract as this can increase the possibility of the balloon pulling through the stoma.

11. Measure the stoma length by following the **MEASURE THE STOMA LENGTH** section.
12. Select the correct MiniSPC™ Button size and place the device following the **DEVICE PLACEMENT PROCEDURE.**

MEASURE THE STOMA LENGTH

CAUTION: Selection of the correct size device is critical for the safety and comfort of the patient. Measure the length of the patient's stoma with a stoma measuring device. The shaft length of the selected device should be the same as the length of the stoma. An inappropriately sized device can cause necrosis, buried bumper syndrome and/or hypergranulation tissue.

1. Please refer to Manufacturer's Directions for Use for the stoma measuring device being used.
2. Be sure to select the appropriate size MiniSPC™ Button for the abdominal wall thickness measured. If the measurement appears to be between two sizes, always select the next larger size MiniSPC™ Button. Once placed, the external flange should rotate easily.

WARNING: UNDER-SIZING THE DEVICE MAY CAUSE EMBEDDING WITH EROSION INTO THE BLADDER WALL, TISSUE NECROSIS, INFECTION, SEPSIS ASSOCIATED SEQUELAE, AND/OR DEVICE FAILURE.

DEVICE PLACEMENT PROCEDURE

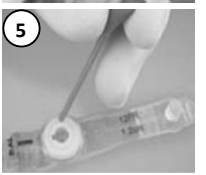
CAUTION: Prior to placement, please inspect all contents of the kit for damage. If the package is damaged or sterile barrier is breached, do not use the product.

CAUTION: Do not attempt to replace the device or check for placement verification until first discussing the procedure with your healthcare professional.

1. Select the correct MiniSPC™ Button size for placement.

NOTE: When replacing a device, stoma length should be periodically measured to ensure the correct MiniSPC™ Button size is being used. If patient size/weight has changed since the device was placed, fit is too tight or too loose, or it has been over six months since the stoma was last measured, it is recommended that the stoma is measured to ensure that device size does not need changed.

2. Prior to placing the MiniSPC™ Button, inflate balloon through the balloon inflation port (see Fig C) using a Luer slip syringe with sterile water to the recommended fill volume. The recommended fill-volume can be found on Table 1 or printed above the balloon inflation port of the device. Remove the syringe and verify balloon integrity by gently squeezing the balloon to check for leaks. Visually inspect the balloon to verify symmetry. Verify that sizing information is appropriate for measured length. Reinsert the syringe and deflate all of the water from the balloon after inspection.
3. Lubricate the tip of the tube with water soluble lubricant. Do not use mineral oil or petroleum jelly. Insert optional introducer into the drainage port if increased stiffness is desired during placement.
4. Gently guide the tube through the stoma and into the bladder until the external flange is flush to the skin.
5. Remove Introducer (if used in step 3).
6. Inflate the balloon with sterile water according to the fill volume in the chart in Table 1.
7. Gently lift the tabs and check for signs of leakage.



NOTE: If leakage is observed, increase balloon volume in increments of 0.5-1 ml. **Do not exceed maximum fill volume.**

Table 1: Balloon Inflation Volumes

Fr Size	Minimum Fill Volume	Recommended Fill Volume	Maximum Fill Volume
14 F	3 ml	4 ml	5 ml
16F	4 ml	6 ml	8 ml
18F	6 ml	8 ml	10 ml

PLACEMENT VERIFICATION

1. If there is any trouble with placement, or any pain, blood, or site trauma occur during device removal or placement, consult with a physician before using the device to confirm proper device placement.
2. Ensure the drainage set clamp is closed and attach the drainage set to the MiniSPC™ Button by lining up the dark line on the drainage set connector with the dark line of the interlock on the MiniSPC™ Button. Fully press the drainage set connector into the MiniSPC™ Button. Turn 3/4 to the right (clock-wise) to lock the drainage set in place (see Fig D).
3. Attach a large diameter catheter syringe to the drainage set. Open the drainage set clamp. Spontaneous return of urine should occur.
4. Placement is confirmed after urine is observed.

WARNING: NEVER INJECT AIR INTO THE MINISPC™ BUTTON.

WARNING: NEVER CONNECT THE DRAINAGE SET TO THE BALLOON INFLATION PORT.

5. When placement is confirmed, full drainage can begin.

NOTE: In the case of an initial placement, consult with your physician regarding proper flushing and drainage procedures immediately following placement.

PLACEMENT CARE INSTRUCTIONS

1. The MiniSPC™ Button should be replaced periodically for optimal performance. Clogging and/or reduced flow are indications of diminished performance. Refer to the TROUBLESHOOTING section for additional signs of reduced performance or failure.
2. Be sure the balloon is within the bladder and the MiniSPC™ Button rotates freely before the drainage begins.
3. The stoma area should be cleansed daily with a mild soap and water. The stoma site should be clean and dry at all times. The MiniSPC™ Button should be rotated daily for site hygiene.

DRAINAGE SET INSTRUCTIONS FOR USE

WARNING: THIS DEVICE HAS THE POTENTIAL TO MISCONNECT WITH SMALL BORE CONNECTORS OF OTHER HEALTHCARE APPLICATIONS. ONLY USE THIS DEVICE TO CONNECT TO COMPATIBLE DRAINAGE DEVICES.

WARNING: THE FUNNEL ADAPTER OF THE DRAINAGE SET HAS THE POTENTIAL TO MISCONNECT TO BREATHING SYSTEM, LIMB CUFF, AND NEURAXIAL CONNECTORS.

1. Prior to use, please inspect all contents of the kit for damage. If the package is damaged or sterile barrier is breached, do not use the product. Obtain another package.
2. The drainage set may be used for gravity drainage of the bladder.
3. Ensure the clamp is closed and attach the drainage set to the MiniSPC™ Button by lining up the dark line on the drainage set connector with the dark line of the interlock on the MiniSPC™ Button. Fully press drainage set connector to insert into the MiniSPC™ Button. Turn 3/4 to the right (clock-wise) to lock the drainage set into place (Fig D).
4. Attach the funnel end of the drainage set to the urine collection device connector being used. Firmly insert the urine collection device connector into the funnel adapter while using a slight rotation to lock in place. Once connected, open the clamp to allow flow.

NOTE: For urine to flow away from the body, position the drainage adapter and collection bag such that it is always lower than the bladder. Improper elevation may result in unintended urine backflow.

WARNING: ONLY TIGHTEN BY HAND. NEVER USE EXCESSIVE FORCE OR A TOOL TO TIGHTEN THE CONNECTOR. IMPROPER USE CAN LEAD TO CRACKING, LEAKAGE, OR OTHER FAILURE.

WARNING: ENSURE DEVICE IS CONNECTED TO A DRAINAGE PORT ONLY AND NOT TO AN IV SET.

WARNING: IF THE DRAINAGE SET IS NOT PROPERLY PLACED AND LOCKED, LEAKAGE MAY OCCUR. WHEN TWISTING THE DRAINAGE SET CONNECTOR, HOLD THE MINISPC™ BUTTON IN PLACE TO AVOID ROTATION WHILE PLACING THE DRAINAGE SET. NEVER INSERT DRAINAGE SET CONNECTOR INTO THE BALLOON INFLATION PORT (FIG C). THIS MAY CAUSE THE INTERNAL BALLOON TO DEFLATE OR LEAD TO BALLOON FAILURE IF IMPROPER CONTENTS ARE INSERTED INTO THE BALLOON.

5. When drainage is complete, remove the drainage set. Close the clamp to prevent leakage while removing the drainage set. Remove the drainage set by holding the MiniSPC™ Button in place, grasp the drainage connector, twist 3/4 turn to the left (counter clock-wise) to unlock (Fig B), and gently remove the drainage set from the MiniSPC™ Button.
6. Flush the device in accordance with frequency and protocol established by your physician. A Luer slip syringe may be inserted directly into the drainage port of the MiniSPC™ Button for flushing. When flushing is complete, snap the MiniSPC™ Button plug in place to keep the lumen clean.
7. Store drainage set in a clean, dry place. A previously used drainage set may be reused for drainage only. It must not be used for flushing.

DRAINAGE SET INSTRUCTIONS FOR USE

WARNING: IN CASE OF FEVER, ABDOMINAL DISTENTION, INFECTION, BLOCKAGE, TISSUE NECROSIS, SITE REDNESS, OR PURULENCE, PATIENTS SHOULD SEE THEIR PHYSICIAN IMMEDIATELY.

WARNING: DO NOT PLACE ANY FOREIGN OBJECTS INTO THE DRAINAGE PORT.

WARNING: DO NOT USE A PREVIOUSLY USED DRAINAGE SET FOR FLUSHING.

Drainage sets are meant to be periodically replaced for optimal performance and cleanliness. AMT recommends that the drainage set be changed at least weekly or as often as indicated by your healthcare professional. Device performance and functionality can degrade over time depending on usage and environmental conditions. Some factors that can lead to reduced longevity include: frequency of use, trauma to the device, and overall drainage set care. Device should be replaced if leakage, cracks, tears, excessive residue build-up, mold, fungus, or other signs of failure are noted. Some usage types can wear down device components quicker than others. If tubing is becoming hardened, replacement is recommended to avoid failure.

PROPER FLUSHING GUIDELINES

Proper flushing techniques and frequency can help prevent tubing blockage, clogs, and tubing failure. Flush the device in accordance with frequency and protocol established by your physician. A Luer slip syringe may be inserted directly into the drainage port of the MiniSPC™ Button for flushing.

UNCLOGGING A DEVICE

First check to make sure that the tube is not kinked or clamped anywhere. If there is a visible clog in the tubing, attempt to massage the device to break up the clog. Insert a syringe filled with sterile solution directly into the drainage port on the catheter and gently push and pull the syringe plunger to free the clog. It may take several cycles of pushing / pulling the plunger to clear the clog. If clog cannot be removed, contact your healthcare professional, as the tube may need to be replaced.

CAUTION: Do not use excessive force or pressure to attempt to clear the clog. This can cause the tubing to rupture.

REMOVAL OF THE MINISPC™ BUTTON

1. Deflate the balloon by attaching the Luer slip tip syringe into the balloon inflation port (Fig. 3) to withdraw the sterile water.
2. Gently remove the device from the stoma site.
3. Replace as necessary following the MiniSPC™ Button directions for use.

NOTE: Spontaneous closure of the stoma may occur within one hour after removal. Insert new device if drainage by this route is still intended.

NOTE: To help prevent unneeded hospital visits, it is recommended that a spare device is kept on hand at all times for replacement in case device failure occurs prior to scheduled replacement.

WARNING: DO NOT CUT OFF THE INTERNAL BOLSTER OR TUBING.

NOTE: The device can be disposed of by following local facility protocol.

TROUBLESHOOTING

While it is expected that you will use your MiniSPC™ Button without any issues, unexpected device problems can sometimes occur. The following section covers a number of performance or functionality related items and how to help prevent these types of occurrences.

A tear has formed: Tears can occur due to contact with a sharp or abrasive object, excessive force, or excessive pressure. Due to the soft, comfortable nature of the material the device is made from, small tears can quickly lead to large tears or device failure. If a tear is noticed on the device, consider replacing device and check for any sources of tension, force, or sharpness that may be leading to the tears occurring.
Balloon inflation valve leakage: Leakage from this valve typically occurs due to residue in the fill-valve. Always use a clean syringe when inflating the balloon and only inflate water through the valve. Leakage can also occur due to valve becoming stuck if syringe is inserted too hard into valve. Insert the syringe into the balloon inflation port if leakage is occurring to attempt to reset valve. Several attempts may be necessary before valve resets.
Leaking of balloon volume: If balloon is deflating, remove balloon from stoma and inflate balloon with recommended fill-volume. Check balloon for leakage by gently massaging tubing and balloon. If no leakage is noted, re-insert balloon back into stoma and re-inflate the balloon to desired fill-volume. Do not exceed maximum fill volume. Only access the balloon inflation port for balloon inflation and deflation. Other uses can result in balloon leakage or device failure. **NOTE:** The balloon is made of a semi-permeable material and can lose a small amount of fill-volume over time depending on environment and usage conditions.

TROUBLESHOOTING

Balloon will not inflate or deflate: Inflation and deflation problems typically occur due to residue blocking the fill-lumen. Always use a clean syringe when inflating the balloon. In some rare occurrences, fungus can grow inside of the tubing and block the fill-lumen. Fungus growth can occur depending on patient environment. If balloon will not deflate, contact your healthcare professional for removal. If deflation problem is the result of fungal growth, eliminating source of fungal growth or anti-fungal medication may be required.

Anti-Leakage valve leakage or blockage: Leakage/blockage of the anti-leakage valve typically occurs due to residue becoming stuck in the valve area, preventing the valve from fully closing. Flush the device in accordance with frequency and protocol established by your physician. The valve can also become inverted in rare cases. Insert drainage set into port to reset valve if this occurs.

Interlock failure or cracked: The interlock has been designed to withstand extreme forces without detaching or cracking. However, the strength of the bond and material can reduce over pro-longed use depending on solutions/drainage used through the device. The device should be replaced if interlock is found cracked, leaking, or separating from the device.

Tubing has reduced flow or has become clogged: Tubing can become blocked due to not properly following the flushing protocol established by your physician, general use of the device, and/or fungus growth. If clogged, refer to the **UNCLOGGING A DEVICE** section for instructions on how to unclog the device. If clog cannot be removed, device may need to be replaced.

Foul smell coming from the device: Foul smells can occur due to not properly flushing the device with sterile water after each use, infection, or other growth forming inside of the device. If a foul smell is noted coming from the device, device should be flushed and stoma site should be gently cleaned with soap and warm water. If foul smell does not go away, it is recommended that you contact your healthcare professional.

Device fit is too tight or too loose: Balloon fit can be adjusted by adjusting balloon inflation within the balloon inflation range in **Table 1**. If balloon fit is too loose, increase balloon fill-volume above recommended but not above max fill-volume. If balloon fit is too tight, decrease fill-volume below recommended but not below min fill-volume. If device does not properly fit with the fill-volume range, a new device length will be needed.

Balloon failure: Early balloon failure can occur due to a number of patient or enivornment factors, including but not limited to: improper balloon fill volume, placement of device, trauma, contact with a sharp or abrasive material, incorrect stoma length measurement, and overall care of the device.

Balloon is misshaped: Be sure to inflate and inspect balloon prior to placement to check balloon symmetry. Balloons becoming misshaped typically occur due to excessive force or tension on the device (pulling device out of stoma while balloon is inflated). Balloons can be gently massaged with fingers back into symmetry if not excessively misshaped. Devices should be replaced if balloon is found excessively misshaped.

Plug will not stay closed: Ensure that plug is being firmly and fully pressed into the interlock connector. If plug is not staying closed, check the plug and drainage-port area for any excess residue build-up. Clean excess residue build-up with cloth and warm water.

Device has become discolored: The device can become discolored over days of use. This is normal during general use of the device.

MRI SAFETY INFORMATION

Non-clinical testing demonstrated that the MiniSPC™ Button is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

MR Conditional

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 1,000-gauss/cm (10-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the MiniSPC™ Button is expected to produce a maximum temperature rise of 1.6°C after 15 minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the MiniSPC™ Button extends approximately 20-mm from this device when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

THANK YOU!

Thank you for choosing AMT. For additional help and information regarding the use of our device, feel free to contact AMT with the contact information on the back of the instructions for use. We are happy to hear your thoughts and help with your concerns and questions.

EN STERILE EO Sterilized Using Ethylene Oxide		Rx Only Prescription Only
2 STERILIZE Do Not Resterilize	2 Single Use Only	Do not use if package is damaged and consult instructions for use
LATEX Not made with natural rubber latex	MR MR Conditional	PHT DEHP Not made with DEHP (Di(2-ethylhexyl) Phthalate)

AMT
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AMT - Innovating. Educating. Changing Lives.™

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