AMS Sphincter 800™ Urinary Control System

Sphincter artificiel AMS 800™ Système de contrôle urinaire

AMS Sphincter 800™ Künstlicher Blasenschließmuskel

Sfintere urinario artificiale AMS Sphincter 800™

Sistema de control urinario Sphincter 800™ de AMS

Sistema de Controlo Urinário AMS Sphincter 800™

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European Union (EU) Authorized Representative:
AMS France
19 bis avenue du Québec
91951 Courtaboeuf Cedex
France
Tel (33) 01-69.59.97.00
FAX (33) 01-69.59.97.29

AMS International Representative Contact List:
AMS U.S.A.
10700 Bren Road West
Minnetonka, MN 55343
U.S.A.
Toll Free 800.328.3881
Tel (1) 952.933.4666
FAX (1) 952.930.6157

AMS Benelux
Toekomstraat 10
1930 Zaventem
Belgium
Tel (32) 02-720.33.93
FAX (32) 02-721.77.71

AMS Canada
55 Regal Road, Unit 3
Guelph, Ontario N1K 1B6
Canada
Tel (1) 800.265.2611
FAX (1) 519.821.1356

AMS France
19 bis avenue du Québec
91951 Courtaboeuf Cedex
France
Tel (33) 01-69.59.97.00
FAX (33) 01-69.59.97.29

AMS Deutschland GmbH
Kronenstraße 3
10117 Berlin
Germany
Tel (49) 30-20.64.390
FAX (49) 30-20.64.39.99

AMS Ibérica S.L.
Avda. de las dos Castillas 33
Edif. Atica 3, Oficina 2a D
28224 Pozuelo de Alarcón (Madrid)
Spain
Tel (34) 91-799.49.70
FAX (34) 91-715.75.26

AMS U.K. Ltd.
9 Ironbridge House
Windmill Place
2-4 Windmill Lane
Hanwell Middlesex, UB24NJ
United Kingdom
Tel (44) 208.606.9955
FAX (44) 208.606.9988

AMS Australia Pty.
Suite 3, Level 5
460 Church Street
P.O. Box 2101
North Parramatta 2150
Australia
Tel 61 2 8838 8800
FAX 61 2 9890 9899

CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

NOTE: For implant procedure information, consult the AMS Sphincter 800™ Urinary Control System Operating Room Manual.

Brief Device Description

The AMS Sphincter 800™ Urinary Control System is an implantable, fluid filled, solid silicone elastomer device used to treat stress urinary incontinence. It is designed to restore the natural process of urinary control. The device simulates normal sphincter function by opening and closing the urethra at the control of the patient. The AMS Sphincter 800 consists of three interconnected components: a cuff, a pump, and a pressure-regulating balloon. The three components are connected with kink-resistant tubing. The AMS Sphincter 800 can be implanted at either the bulbous urethra or the bladder neck.

Indications for Use

The AMS Sphincter 800 is used to treat urinary incontinence due to reduced outlet resistance (intrinsic sphincter deficiency) following prostate surgery.

Contraindications

1. This device is contraindicated in patients whom the physician determines to be poor candidates for surgical procedures and/or anesthesia due to physical or mental conditions.
2. This device is contraindicated in patients with urinary incontinence due to or complicated by an irreversibly obstructed lower urinary tract.
3. This device is contraindicated in patients with irresolvable detrusor hyperreflexia or bladder instability.

Warnings

1. Patients with urinary tract infections, diabetes, spinal cord injuries, open sores, or skin infections in the region of the surgery have an increased risk of infection associated with a prosthesis. Appropriate measures should be taken to reduce the likelihood of infection.

   Infection that fails to respond to antibiotic therapy may result in removal of the prosthesis. Infection followed by explantation of the device may result in scarring which may make subsequent reimplantation more difficult.
2. Erosion may be caused by infection, pressure on the tissue, improper cuff sizing, improper balloon selection, tissue damage, and component misplacement. The cuff may erode around the urethra or bladder neck. The control pump may erode through the scrotum. The pressure-regulating balloon may

erode into the bladder. Acute urinary tract infection can interfere with proper functioning of the device and may lead to erosion of the urethra in the cuff area. Failure to evaluate and promptly treat the erosion may result in a substantial worsening of the condition leading to infection and/or loss of tissue.

3. Poor bladder compliance or a small fibrotic bladder may require some measure of intervention including, in some cases, augmentation cystoplasty before implanting the prosthesis.
4. Patients with urge incontinence, overflow incontinence, detrusor hyperreflexia or bladder instability should have these conditions treated and controlled (or resolved) prior to implantation of the device.
5. Do not pass a catheter or any other instrument through the urethra without first deflating the cuff and deactivating the device to prevent potential damage to the urethra or the AMS Sphincter 800.
6. This device contains solid silicone elastomers. This device does not contain silicone gel. The risks and benefits of implanting this device in patients with documented sensitivity to silicone should be carefully considered.
7. Surgical, physical, psychological, or mechanical complications, if they occur, may necessitate revision or removal of the prosthesis. Removal of the device without timely reimplantation of a new device may complicate subsequent reimplantation. The timing of reimplantation should be determined by the treating physician based on the patient's medical condition and history.
8. Product wear, component disconnection or other mechanical problems may lead to surgical intervention. Mechanical complications may include malfunctioning of the components and leakage of fluid. Any mechanical malfunction that does not permit the transfer of fluid from the cuff to the balloon may result in overflow obstruction. Mechanical events should be evaluated carefully by the treating physician and the patient should consider risks and benefits of treatment options, including revision surgery.
9. Previous patient history of adverse reaction(s) to radiopaque solution precludes its use as a filling medium for the prosthesis. Instead, saline should be used to fill the device.

PRECAUTIONS

Patient Related

1. Patient selection requires thorough preoperative consultation and evaluation by the physician.
2. Patients should be counseled in order to have a realistic expectation of the physical, psychological, and functional outcome of the implantation of an AMS Sphincter 800. Although the prosthesis is designed to restore urinary control, some patients continue to have a degree of incontinence after this procedure.

3. Patients may experience pain when the device is activated in the postoperative period and during the period of initial use. Cases of chronic pain associated with device have been reported. Pain with a severity or duration beyond what is expected may require medical or surgical intervention. Patients should be counseled on expected postoperative pain including severity and duration.
4. Tissue fibrosis, previous surgery, or previous radiation therapy in the area of the implant may preclude implantation of a cuff at the bulbous urethra or bladder neck.
5. Any progressively degenerative disease, e.g. multiple sclerosis, may limit the future usefulness of the implanted prosthesis as a treatment for the patient's urinary incontinence.
6. Adequate manual dexterity, strength, motivation, and mental acuity are required for proper use of the device.
7. Trauma or injury to the pelvic, perineal or abdominal areas, such as impact injuries associated with sports, can result in damage to the implanted device and/or surrounding tissues. This damage may result in the malfunction of the device and may necessitate surgical correction including replacement of the device. The physician should advise patients of these possibilities and warn them to avoid trauma to these areas.

Surgery Related

1. Improper cuff sizing, improper balloon selection, or other causes may result in tissue erosion, migration of components, or continued incontinence.
2. Component migration can occur if the cuff is sized improperly, if the pump or balloon is not positioned correctly, or if the tubing lengths are incorrect. Migration can result in pain, complications, device malfunction and surgical revision.
3. Unsuccessful outcomes may result from improper surgical technique, improper sterile technique, anatomical misplacement of components, improper sizing and/or filling of components.
4. Although reinforced tubing has been designed to be more resistant to tubing kinks, tubing kinks may still result from tailoring the connecting tubing to an improper length during the implant procedure.

Device Related

1. If the deactivation valve is closed when the cuff is inflated, fluid cannot transfer from the cuff to the balloon and sustained outflow obstruction may arise as a result:
   a. In the event of large pressures within the bladder, automatic pressure relief that normally occurs with the device would be prevented. Cycling the device can relieve the outflow obstruction.
   b. Cycling the device may be difficult if deactivation occurs when the pump bulb is deflated. If unable to cycle the device, squeezing the sides adjacent to the deactivation button will allow fluid to fill

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the pump bulb and then the pump can be cycled normally.

c. Release of the deactivation valve may require greater pressure than that used to cycle the device.

2. System pressure changes may occur over time if you fill the balloon with radiopaque solution of incorrect concentration. Follow the instructions in the Operating Room Manual to prepare the radiopaque solution with the correct concentration.

ADVERSE EVENTS

A prospective clinical study was conducted to demonstrate the safety and efficacy of the AMS Sphincter 800 Urinary Control System. A total of 87 patients were enrolled in the study and 85 patients were implanted with the device. During the study, 26 patients experienced 43 device related adverse events. Table 1 lists the device related adverse events reported during the study.

Table 1: AMS Sphincter 800 Prospective Clinical Study Device Related Adverse Events

				Interventions*		
Adverse Event Category	Total Events	Patients with AE	Events Resolved	None Reported	Medical**	Surgical
Impaired Device Function	7	6	4	2	2	4
Pain/Discomfort	6	5	4	3	3	1
Delayed Wound Healing	5	5	5	2	3	0
Bladder Spasms	2	2	0	0	2	0
Difficult Activation	2	2	2	1	1	0
Migration	3	3	1	2	0	1
Tissue Erosion	2	2	2	0	0	2
Difficult Deactivation	1	1	1	0	1	0
Infection	2	2	2	0	0	2
Recurrent Incontinence	3	3	3	1	0	2
Fistula Formation	1	1	1	0	0	1
Hematoma	1	1	1	0	1	0
Swelling	2	2	2	0	2	1
Hydrocele	1	1	1	0	1	1
Tissue Erosion/Infection	1	1	1	0	0	1
Patient Dissatisfaction	1	1	1	0	0	1
Positional Incontinence	1	1	0	1	0	0
Wound Infection	1	1	1	0	1	0
Urinary Retention	1	1	1	0	1	0

*Events may have been addressed with more than one type of intervention.

**Medical interventions included: medication, education, frequent device deactivation, dressing changes and catheterization.

CLINICAL STUDIES

A prospective, multi-center, non-randomized clinical study was undertaken to demonstrate that the AMS Sphincter 800 can be surgically implanted without serious adverse sequelae, provides an acceptable level of continence and enhances quality of life. Each patient served as their own control. Efficacy data and safety data related to adverse events, revision surgery, diagnoses and health status evaluations were captured on case report forms. Patient self-evaluations related to health status and non-illness specific quality of life were measured on two validated outcome instruments. Patient and physician assessments of continence were measured on a recognized, standardized non-validated instrument.

Eighty-seven (87) male patients were enrolled in the study of which 85 patients were implanted with the device during the study. Patients available at the follow-up intervals were 6-months (n=67), 12-months (n=60), 18-months (n=55), and 24-months (n=41). Patients diagnosed with intrinsic sphincter deficiency (ISD) resulting from prostate surgery

were eligible for enrollment. Patients with a history of allergy/sensitivity to silicone, pre-existing autoimmune or connective tissue disease or active urogenital infection were excluded from the study.

Endpoints

The primary effectiveness endpoint evaluated the effect of the prosthesis on patient quality of life using the *Incontinence Impact Questionnaire*, an incontinence-specific quality of life questionnaire. The primary safety endpoint evaluated the five-year revision-free rate using a Bayesian hierarchical model. The safety endpoint was a five-year revision-free rate equivalent to 75% using a 10% delta with a two-sided 95% lower bound greater than 65%.

Incontinence Impact Scores

The primary effectiveness endpoint was a reduction in Incontinence Impact Score from pre-to post-implant status. Incontinence impact was measured pre- and post-implant at 6, 12, 18, and 24 months. Thirty-nine (39) patient answered the *Incontinence Impact Questionnaire* (IIQ) at 24-month follow-up. The IIQ is a 30-item, self-administered questionnaire designed to assess the impact of urinary incontinence on several subscales including physical, emotional, and social. The IIQ used in the study was developed from a validated instrument.[1] The mean pre-implant score was significantly higher ($p > 0.0001$) than mean scores at all follow-up visits. Therefore, the impact of incontinence was reduced for patients following AMS Sphincter 800 implantation and the primary objective was met.

Physician and Patient Assessment of Continence

Physician assessed continence was 63.6% dry and 34.1% required some additional protection at one-year follow-up (n=43). At two-year follow-up (n=30), 73.3% were dry and 23.3% required some additional protection. Patient assessed continence was 61.7% dry and 36.7% required some additional protection at one year follow-up (n=60). At two-year follow-up (n=41), 65.9% were dry and 31.7% required some additional protection. No significant difference existed between physicians' assessment and the patients' assessment of their incontinence.

Patient Evaluation of Health Status, and Self-esteem

General Quality of Life as measured by the *Health Status Questionnaire* and the *Rosenberg Self-esteem Questionnaire* was evaluated at pre- and post-implant at 6, 12, 18, and 24 months. Thirty-eight (38) patients answered the *Health Status* and *Rosenberg Self-esteem Questionnaires* at 24-month follow-up. The self-administered *Health Status Questionnaire*[2] was used to assess non-illness specific parameters such as physical functioning, social functioning, energy/fatigue, pain, health perception, and emotional problems. A high score indicates that overall health was perceived to be high. The mean score was 596 at pre-implant and 612 at two-year follow-up. No significant difference in health status scores was observed during the study. The self-

administered *Rosenberg Self-esteem Questionnaire*[3] was used to assess changes in patient self-esteem. The range of possible scores is 0-6, with a score of 6 indicating high self-esteem. The mean score at implant was 3.5 and at two-year follow-up was 4.1. The increase in mean score indicates a more positive self-esteem following AMS Sphincter 800 implant. The device did not have an adverse effect on sexual function. Some patients with improved continence following implant also reported increased sexual activity. The positive impact of the device on patient's lives measured in the clinical study is consistent with results obtained by other authors.[4,5,6]

Surgical Revisions

A revision is a surgical intervention related to the function, placement, or site reaction to the implanted device. For the 85 patients implanted with the device followed under the prospective clinical study, 14 patients (16.5%) experienced a total of 15 revisions up to 24 months following implant. One patient had two revisions. Three (3) revisions were due to mechanical malfunction. Two (2) revisions were due to recurrent incontinence. Two (2) revisions were due to erosion. Two (2) revisions were due to infection. One (1) revision each (total = 6) was due to migration, pain, erosion/infection, persistent incontinence/patient dissatisfaction, recurring incontinence/ malfunction, infection/pain/urethrocutaneous fistula. Multiple reasons were provided for some revisions. Four of the 14 patients who experienced revisions elected to have the device removed and 10 elected to have the device replaced. The probability of remaining revision-free 24 months following implant was 79.5% (95% CI with 95% lower confidence bound 69.8%) based on the prospective clinical study.

Additional data on the number of surgical revisions and their reasons were collected under two retrospective studies. Each of these studies are briefly described below and comparisons of revision data of these two retrospective studies and the prospective study are presented in Tables 2 and 3.

Patient Information Form (PIF) Study – The PIF study was a retrospective analysis of patients implanted (n=12,713) in the U.S during the five-year period 1995-1999. The study examined PIF data voluntarily sent to the manufacturer by the implanting physician for original implants and revisions. PIF data is required to be on file with the manufacturer in order to be eligible for product replacement. Revision data presented in Table 2 and Table 3 below are based on a total of 2,116 revisions reported for 2,014 patients that required one or more revisions during the five-year period of the study.

Retrospective Clinical Study – The retrospective clinical study was an analysis of patients implanted (n=390) in the U.S. between 1987-1990. The study examined pre- and post-implant medical records and follow-up data collected by questionnaires and physician examinations. Post-implant data was available for 356 patients. The study followed patients for up to ten years (mean: 4.1 years; range: 0.03-10.3 years). The revision data

presented in Table 2 and Table 3 below are based on a total of 317 revisions reported on 164 patients that required one or more revisions during the ten-year period of the study.

The data in Table 2 presents the percentage of patients revised during the specified follow-up period, the average number of revisions conducted on patients requiring a revision and the number of revisions expected per 100 patients for these studies in comparison with the data of the prospective clinical study.

Table 2: Comparison of Revision Data from Three Different Clinical Studies

	Prospective Study (85 pts. over 24 months)	PIF Study (12,713 pts. over 5 years)	Retrospective Study (356 pts. over 9 years)
% pts. revised	16.5% (14/85)	15.8% (2014/12713)	46.1% (164/356)
avg.. # of revisions per pts. revised	1.07 (15/14)	1.05 (2116/2014)	1.93 (317/164)
# of revisions per 100 pts.	18 (15/85)	17 (2116/12713)	89 (317/356)

Table 3 shows revision data stratified by each reported reason for revision from three different studies of male patients implanted with the AMS Sphincter 800. Under the PIF Study and Retrospective Study multiple reasons were sometimes provided for a single revision. Therefore, in order to stratify this revision data by reason, all occurrences were included and presented as "% reason." The total number of reasons therefore exceeds the total number of revisions reported for these studies.

Table 3: Reasons for Revision in Three Different Studies

Revision Reason[a]	Prospective Study (n=85)		PIF Study (n=12713)		Retrospective Study (n=356)	
	% revisions	(# revisions)	% reason	(# reasons)[b]	% reason	(# reasons)
Infection	2.4%	(2)	2.3%	(297)	8.1%	(29)
Infection/erosion	1.2%	(1)	----		----	
Erosion	2.4%	(2)	3.6%	(451)	22.5%	(80)
Recurring Incontinence	2.4%	(2)	5.7%	(724)	42.4%	(151)
Fluid Loss	----		2.3%	(298)	9.3%	(33)
Fluid Transfer Impaired	----		0.3%	(38)	----	
Pressure too low	----		1.1%	(140)	----	
Mechanical Malfunction	3.5%	(3)	0.7%	(89)	13.8%	(49)
Migration/ Malposition	3.5%	(3)	0.4%	(46)	4.8%	(17)
Iatrogenic Complications	----		0.4%	(51)	0.6%	(2)
Reimplantation/ Replacement	----		----		3.1%	(11)
Pain	1.2%	(1)	0.2%	(22)	1.4%	(5)
Patient Dissatisfaction	1.2%	(1)	0.2%	(27)	1.7%	(6)
Other[c]	----		2.4%	(305)	----	
Not Indicated	----		1.9%	(242)	----	

a Note that some adverse events in the table such as fluid loss, pressure too low, fluid transfer impaired and malposition could fall into the category of mechanical malfunction or iatrogenic error. Since information is not available to place them in either category, they are listed separately.

b Numbers of reasons can vary for the same percentage due to rounding.

c Other includes: double cuff, pressure too high, unable to activate, unable to deactivate, atrophy, difficult to operate, urinary retention, air in the system, hematoma.

Device Survival

Although it is not possible to predict exactly how long an implanted prosthesis will function in a particular patient, American Medical Systems, Inc. gathered data from two sources on device removals and revisions to help gain insight into product performance over time. Figure 1 presents device survival results from the

prospective clinical study and a Bayesian analysis that uses data from the prospective clinical study and the PIF Study to estimate device survival at five years.

Prospective Clinical Study – A device survival curve was calculated from data collected during a prospective clinical study (n=85) with two-year follow-up. Using Kaplan-Meier analysis, the two-year revision-free rate for the AMS Sphincter 800 was 79.5% (95% CI with 95% lower confidence bound 69.8%).

Bayesian Analysis – A Bayesian hierarchical model was used to evaluate device safety in the prospective clinical study. The Bayesian model estimated device survival using historical data (PIF Study n=12,713) on the AMS Sphincter 800 and prospective clinical study data (n=85) on the AMS Sphincter 800. A log-normal distribution fit the AMS Sphincter 800 historical data. Based on the log-normal hierarchical model, it was estimated that the five-year revision-free rate for the AMS Sphincter 800 is approximately 73.8% with 95% CI ranging from 67.3% to 79.6%. The results met the primary safety endpoint for the clinical study of a five-year revision free rate at 75% using a 10% delta with two-sided 95% lower bound greater than 65%.

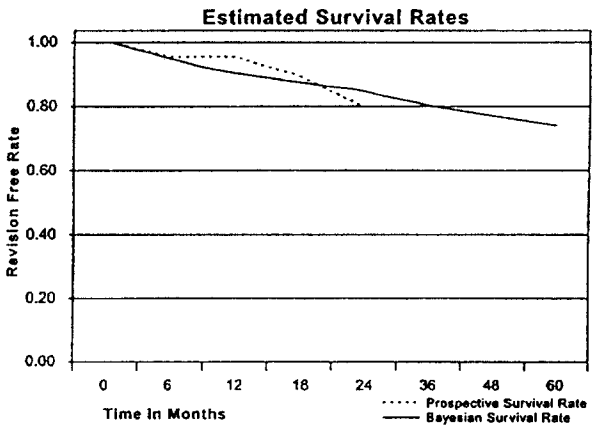

Figure 1: Estimated Survival Rates for the AMS Sphincter 800

DEVICE USE

Retrospective Clinical Study – The study included male AMS Sphincter 800 patients (n=390) implanted between 1987-1990. Data from this study was used to estimate the device use for patients (n=356) with available data through 1997 (range: 0.03-10.3 years). For the retrospective study, "device use" means the span of time from implant to removal, including revisions. Life table analysis indicated that the probability for a 9-year span of device use was 83.9%. Thirty-three (33) of the 356 patients had their device removed. The remaining 323 patients had a functioning device at last contact.

PATIENT COUNSELING INFORMATION

Patients should be counseled in order to have a realistic expectation of the physical, psychological and functional outcome of the implantation. The risks, benefits and potential adverse events of all available treatment options should be discussed with the patient and considered by the physician and patient when choosing a treatment option.

An appropriate patient history, including history of personality disorders, and diagnostic work-up should be a part of the patient decision making process.

Some patients may become dissatisfied by the presence of the prosthetic device in their body. This issue should be discussed with the patient prior to the surgery. Patient dissatisfaction may lead to device removal. Patients should also be aware that the AMS Sphincter 800 is not considered to be a lifetime implant.

It is also important that the physician discusses with the patient the possibility of an allergic reaction to the materials in the device (See Silicone Information).

Silicone Information

This device is composed of a number of materials, including solid silicone elastomers and a fluorosilicone lubricant. Silicone gel is not a component in the materials of this device.

Solid silicone elastomers have been commonly used in a variety of biomedical devices for over 40 years. Silicone fluids have an extensive history of use in medical devices.

Scientific literature has included reports of adverse events and other observations in patients with implantable silicone devices. As reported, these events/observations indicate "allergic-like" symptoms and in other cases a symptom complex associated with immunological disorders. No casual relationship has been established between these events and silicone elastomer or fluorosilicone lubricant.

There are reports of malignant tumor formation in laboratory animals only associated with implants of relatively large size. Many different materials are associated with this effect in animals, silicone elastomers among them. No such effect has been described in humans.

Extensive testing has been conducted on all materials that comprise the AMS Sphincter 800. This testing has indicated no toxicological response attributable to the materials. However, some of the materials caused minor irritation when implanted in animals.

Silicone elastomer particulate shedding and particulate migrations to regional lymph nodes have been reported in the literature on penile implants. There are no known clinical sequelae to this phenomenon.

Magnetic Resonance Imaging (MRI) Information

Several studies regarding MRI and AMS prostheses, including the AMS Sphincter 800, have concluded that the presence of an AMS prosthesis will not produce harmful effects during scanning. These studies were conducted by Robert C. Lange, Ph.D., Yale University and Frank G. Shellock, Ph.D., Cedars-Sinai Medical Center, Los Angeles. Dr. Lange produced his study for American Medical Systems and Dr. Shellock produced his studies independently for publication in the *American Journal of Roentgenology* (AJR) and *Radiology*.[7,8,9,10]

In these studies, the metallic components in AMS prostheses were subjected to magnetic field strengths up to 1.5 Tesla and showed no unsafe magnetic interaction.

The small stainless steel components in AMS prostheses may distort the uniform magnetic field in the vicinity of the implant, although it is unlikely that these components will interfere with normal MRI. However, the complete compatibility profile of these products within a MRI field has not been established.

Inventory Returns and Product Replacement Information

A Patient Information Form (PIF) must be filled out and filed with AMS at the time of implant to activate the product warranty. Before returning any components, whether explanted or unused (sterile or nonsterile), customers must fill out the Return Goods Form located on the last page of the Patient Information Form.

Follow all of the instructions on the form carefully, and be sure that the components have been thoroughly cleaned before returning them to AMS. Request an AMS Product Return Kit from the AMS Customer Service Department to return any explanted components to AMS.

In all cases, obtaining credit or percentage of credit for a returned component is subject to approval under the terms of the AMS Return Goods Policy and the AMS Product Replacement Policy. For complete information regarding these policies, contact the AMS Customer Service Department.

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