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Swanson™

Flexible Hinge Toe Implant

Operative technique

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Swanson Flexible Hinge Toe Implant
with Swanson Flexible Hinge Grommet

Operative technique presented by
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U.S. Patent No. 3,875,594.
U.S. Patent No. 4,158,893; 4,198,713

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Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this operative technique and the package insert is available on the website listed.

Intended use

Flexible implant description

The Swanson Flexible Hinge Toe Implant† is a double-stemmed flexible hinge implant designed to restore function to the metatarsophalangeal joints disabled by rheumatoid, degenerative, or post traumatic arthritis. In the first metatarsophalangeal joint, the implant is used in cases of moderate to severe hallux valgus deformity secondary to rheumatoid arthritis, or to senile degenerative arthritis and in cases of bony destruction on both sides of the joint. In the lateral metatarsophalangeal joints, the implant is used in cases of dislocation and extension contracture of the metatarsophalangeal joint, in cases of bone destruction of one or both joint surfaces as in rheumatoid arthritis, and in cases of dislocation resulting from resection of the base of one or both joint surfaces as in rheumatoid arthritis. The Swanson Flexible Hinge Toe Implant is made of silicone elastomer and the design of this implant is based on that of the load distributing, flexible hinge finger joint implant. The midsection, however, is thicker and wider to meet the anatomical and physiological requirements of the metatarsophalangeal joint. The proximal (longer) stem fits into the intramedullary canal of the metatarsal and the distal (shorter) stem into the proximal phalanx. The flexural concavity or open portion of the hinge is placed superiorly or dorsally to allow greater range of dorsiflexion of the toe. The proximal and distal stems have a rectangular cross section to help provide rotational stability in the intramedullary canals.

The Swanson Flexible Hinge Toe Implant is available in two stem sizes, standard and small. Sizes 0 through 7 (standard design) and OS through 5S (small stem design) will adequately meet most operative requirements in the first metatarsophalangeal joint. Sizes 0 through 7 are usually preferred in the lateral toe joint. In the small stem design, the hinge portion is identical to the standard implant but the stems are proportionately smaller for use in those cases in which less reaming of the intramedullary canal is required to insert an implant. Three separate sizing sets (supplied non-sterile and not suitable for implantation) corresponding to sizes 0 through 7 for use in the first toe, sizes 0S through 5S for use in the lateral toes, are available for proper size determination during surgery.

Grommets

The Swanson Flexible Hinge Toe Joint Grommet†† is a thin titanium shield designed for use with the Swanson Flexible Hinge Toe Implant in rheumatoid patients where cutting or abrasion of the flexible implant from contact with thin, sharp bone edges can occur, or in patients who have high activity levels. It is contoured to conform to the shape of the midsection of the flexible implant and is fabricated from unalloyed titanium for surgical application. The distal grommet is used on the distal stem and the proximal grommet is used on the proximal stem to protect the implant from biomechanical shearing forces of sharp bone edges during joint motion. Grommets are available in 12 sizes corresponding to sizes 0 to 5 and OS to 5S of the Swanson Flexible Hinge Toe Implants. The outer surface of each grommet is marked with a numeral, indicating the size of flexible hinge toe joint implant the grommet fits, as well as the letters “P” or “D,” indicating whether it is a proximal or distal grommet.

†U.S. Patent No. 3,875,594.
††U.S. Patent No. 4,158,893; 4,198,713

Indications and contraindications

Indications

Use of the Swanson Flexible Hinge Toe Implant may be considered:

- In cases of rheumatoid arthritis presenting a moderate to severe hallux valgus deformity, lateral toe involvement, radiographic evidence of erosion, cyst formation and narrowing of the first metatarsophalangeal joint and contractual deformities.
- In cases of severe senile hallux valgus deformity.

NOTICE

Care must be taken to preserve part of the head to prevent shift of the weight bearing to the second toe.

- In cases of moderate to severe hallux valgus deformity secondary to degenerative or post-traumatic arthritis.
- For revision of previous procedures when there is evidence of bony destruction involving both sides of the joint and for revision of failed single stem arthroplasty.
- In cases of rheumatoid arthritis of the lateral toes, presenting moderate to severe deformity and radiographic evidence of erosion, cyst formation, and narrowing of the metatarsophalangeal joint.

The use of a Swanson Flexible Hinge Toe Grommet is indicated in selected patients to prevent cutting of the implant by sharp bone edges. Grommets can be used both distally and proximally to protect the surfaces of the flexible implant.

Contraindications

- Infection
- Physiologically or psychologically inadequate patient
- Inadequate skin, bone, or neurovascular status
- Irreparable tendon system
- Possibility for conservative treatment
- Growing patients with open epiphyses
- Patients with high levels of activity

Each patient must be evaluated by the surgeon to determine the risk/benefit relationship.

Operative technique

Stryker does not recommend a particular operative technique when using the implant. Proper operative procedures and techniques are necessarily the responsibility of the medical profession. Each surgeon must evaluate the appropriateness of the technique used based on personal medical training and experience. A description of the procedure used by Alfred B. Swanson, M.D. follows.

First metatarsophalangeal joint implant arthroplasty incision and exposure

The joint is exposed through a slightly curved, longitudinal incision made over the dorsomedial aspect of the first metatarsophalangeal joint. Additional longitudinal incisions are used when reconstruction of the lateral toes is indicated as frequently needed in a rheumatoid foot. Care must be taken to avoid injury to the small dorsal sensory nerves and veins in the area. The fascia and medial capsule of the joint are exposed and incised medial to the extensor hallucis longus tendon to prepare a capsuloligamentous flap for later closure and correction of the deviation deformity. This flap is usually proximally based on the proximal phalanx. If the anatomical attachments appear weakened, these can be reinforced with a suture through the bone either proximally or distally. If a bursa is present, it is resected. The metatarsophalangeal joint is opened by flexing the toe and incising the dorsal capsular reflections. The capsular attachments to the neck of the metatarsal contain an important vascular supply to the bone and must be protected.

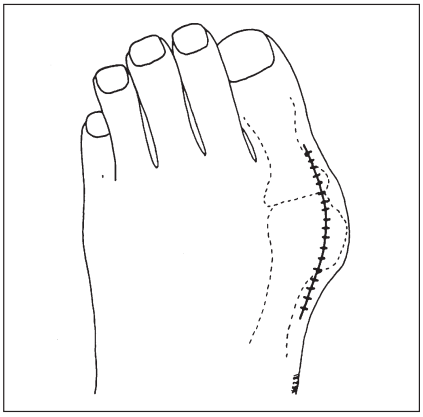


Figure 1
A dorsomedial approach through a slightly curved longitudinal incision along the medial aspect of the metatarsophalangeal joint is used for surgery of the great toe.

Bone preparation

The head of the first metatarsal is excised distal to the metaphyseal flare at the longest diameter of themetatarsal head. A sagittal saw or other power equipment is used to resect this portion of the head in 10° valgus to conform to normal valgus. This way, the implant will not be pinched by the lateral bone edge. The intramedullary canal is shaped in a rectangular fashion to accept the implant stem. An air drill, broach, curette, or rasp may be used. A portion of the base of the proximal phalanx is removed to provide a wider joint space.

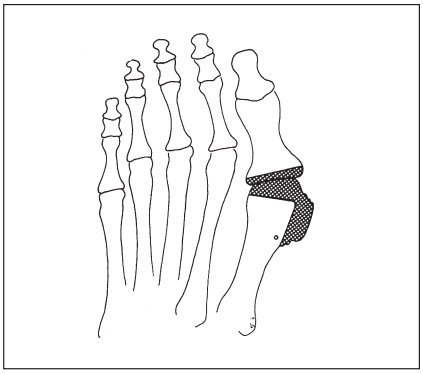


Figure 2
The metatarsal head is excised distal to the metaphyseal flare at the largest diameter of the head with a 10° valgus angle. The base of the proximal phalanx may be removed to provide a wider joint space.

Implant insertion

After the capsular sutures are placed and the wound is copiously irrigated, the grommets are firmly seated if used. The proximal (longer) stem of the implant is inserted in the intramedullary canal of the first metatarsal with the open portion of the hinge positioned dorsally. The toe is then flexed and the distal (shorter) stem is inserted into the proximal phalanx. The proper size implant is determined by the size of the remaining metatarsal and the intramedullary canal.

⚠ CAUTION

Reshaping of the implant should be avoided because it can compromise or destroy the structural integrity and the functionality of the implant.

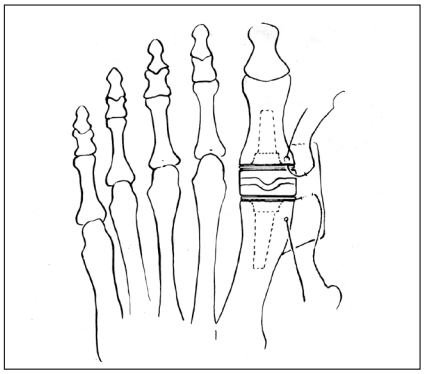


Figure 3
A medial capsuloligamentous flap is carefully prepared and later reattached to bone either proximally or distally or both with 3-0 Dacron sutures to correct the valgus deformity.

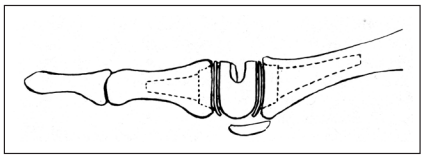


Figure 4
The implant and grommets should fit flush with the cut bone ends without protruding medically or laterally or dorsally or plantarly.

Bone preparation

The head of the metatarsal is resected at the metaphyseal flare with sagittal saw or other power equipment to obtain a smooth transverse osteotomy. The intramedullary canal of the metatarsal is prepared to receive the implant stem, using a hand broach or the air drill with a small leader point burr to avoid perforation of the canal wall.

A portion of the base of the proximal phalanx is removed to provide a wider joint space. The amount of bone removed is dependent upon the degree of contracture preoperatively. All bone edges that contact the implant are left smooth. The appropriate size implant is selected to obtain a snug fit of the stem in the intramedullary canals and to maintain the appropriate joint space.

NOTICE

A non-sterile set of sizing units is available to assist in size determination during surgery.

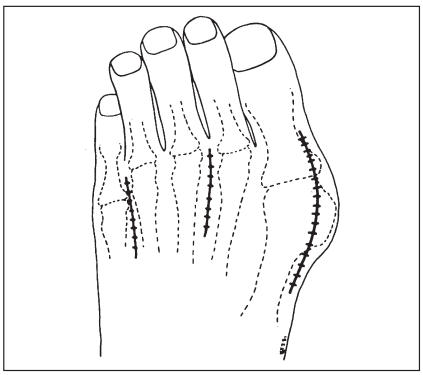


Figure 5
The metatarsal heads are exposed through separate longitudinal incisions placed in intermetatarsal area.

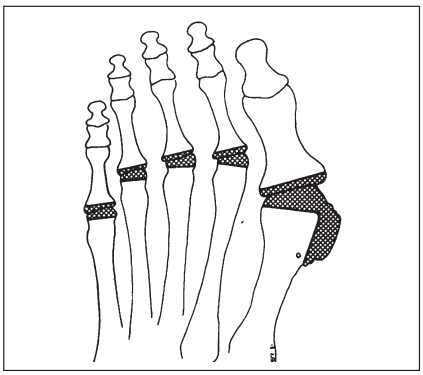


Figure 6
The head of the metatarsal is resected at the metaphyseal flare.

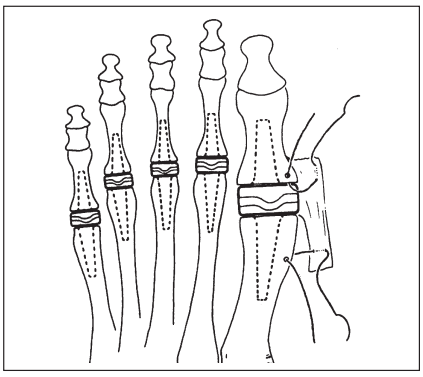


Figure 7
The appropriate size implant is selected to obtain a snug fit of the stems in the intramedullary canals and to maintain the appropriate joint space. Firm reattachment to bone of a loose medical capsule either proximally or distally is of absolute importance for correction of valgus deformity.

Bone edges are carefully smoothened. A trial fit is made with the appropriate color-coded sizer. The implant should fit well into the canal so that the transverse midsection of the implant abuts against the bone ends. The end of the implant stems must not impinge against the end of the intramedullary canals. When the lateral metatarsal heads are not resected, it is important to retain a portion of the first metatarsal head to avoid shifting of the weight bearing to the second metatarsal head. In these cases, to obtain the necessary joint space, additional bone is removed from the base of the proximal phalanx. In patients selected to receive titanium grommets, the sizer is removed and the bone canals are prepared to allow a press-fit of the appropriate size grommet. The resected surfaces of the metatarsal and proximal phalanx are shaped so that the grommet fits well into the bone and the shoulders seat directly against resected bone without protruding so that contact with overlying soft tissue is avoided. The grommet sizing corresponds to the implant sizing. Final seating of the grommet is done by gentle pressure or tapping with the grommet seater or a curved instrument held against the exposed surface of the grommet. This is done with care to avoid bending or distorting the grommet. If too loose, the next larger size is selected. When necessary, using a grommet one size larger than the flexible implant is permissible but a grommet smaller than the implant size is never used. With grommets in place, the sizer is inserted in the joint space and flexion-extension assessed.

⚠ CAUTION

Fitting of the grommet requires a good press-fit and presence of adequate bone stock. It must be accurately centered, otherwise it may impinge the intramedullary canal on one side and could cause bone resorption. In certain cases of severe metatarsophalangeal joint dislocation, considerable bone must be removed to obtain joint reduction and the implant should be used without the grommet. The seating must be exact with regard to centering and rotation. The joint space must be adequate to accommodate the implant midsection. An evaluation of how well the implant/grommet fits in the joint space should be made in both flexion and extension. The implant must slide and not be impinged by the grommet. Impingement is usually caused by the joint being too narrow. The principle of the flexible hinge as a dynamic joint spacer must be respected. The grommet and sizing unit are removed to permit soft tissue reconstruction.

Implant insertion

The wound is irrigated with saline to remove debris and bony fragments. As in the first metatarsophalangeal joint, the proximal (longer) stem of the implant is inserted into the intramedullary canal of the metatarsal; with the open portion of the hinge positioned dorsally, the toe is then flexed and the distal (shorter) stem is inserted into the proximal phalanx. Reshaping of the implant should be avoided.

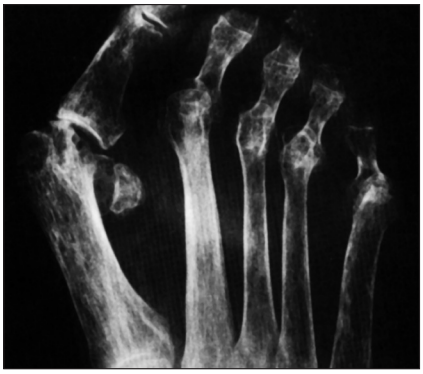


Figure 8
Right foot preoperative radiograph of a 61-year-old rheumatoid arthritis patient shows severe hallux valgus deformity with erosive arthritic changes at metatarsophalangeal joint. The lateral toes show dislocation of metatarsophalangeal joints with reasonable bone stock.

Important points to observe

- Using the color-coded sizing set as a guide, select the largest implant that the bone can accommodate, at the same time being very careful that the implant is well seated.
- Rinse the implant and grommet thoroughly with saline solution before insertion.
- Blunt instruments should be used with a “no touch” technique when inserting Swanson Flexible Hinge Toe Implants and Swanson Flexible Hinge Toe Joint Grommets to avoid traumatization of the implant and contamination by foreign bodies.

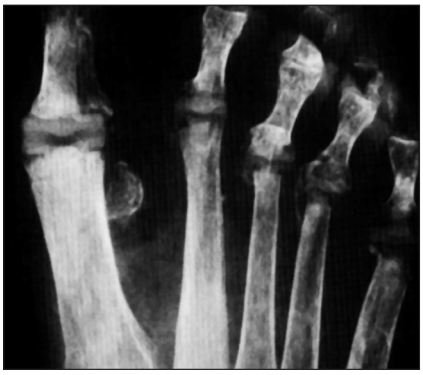


Figure 9
Postoperative radiograph shows correction of deformities of the great toe and the lateral toes following flexible (silicone) implant resection arthroplasty.

Explant information

If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer, using the contact information located on the back cover of this operative technique, to receive instructions for returning the explanted device to the manufacturer for investigation.

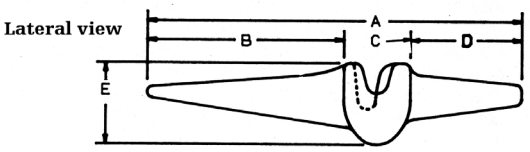
Postoperative care

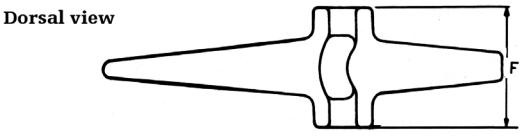
Postoperative care is the responsibility of the medical professional.

Ordering information

Typical dimensions

Size	A	B	C	D	E	F
7-0	28.1mm	14.2mm	3.9mm	9.9mm	4.7mm	8.5mm
6-0	31.6mm	16.0mm	4.4mm	11.2mm	5.3mm	9.6mm
5-0	34.8mm	17.7mm	4.8mm	12.3mm	6.0mm	10.7mm
4-0	38.3mm	19.4mm	5.3mm	13.6mm	6.7mm	11.8mm
3-0	41.7mm	21.2mm	5.7mm	14.7mm	7.1mm	12.8mm
2-0	45.4mm	23.1mm	6.2mm	16.1mm	7.7mm	14.0mm
OS	37.6mm	19.3mm	6.6mm	11.9mm	8.3mm	15.9mm
0	48.6mm	23.7mm	6.6mm	18.3mm	8.3mm	15.9mm
1S	40.2mm	20.9mm	7.2mm	12.4mm	8.9mm	16.6mm
1	52.2mm	26.0mm	7.2mm	18.9mm	8.9mm	16.6mm
2S	43.0mm	22.7mm	7.7mm	12.9mm	9.4mm	17.1mm
2	55.8mm	28.3mm	7.7mm	19.7mm	9.4mm	17.1mm
3S	45.6mm	24.2mm	8.3mm	13.4mm	10.2mm	18.0mm
3	58.9mm	30.5mm	8.3mm	20.1mm	10.2mm	18.0mm
4S	48.3mm	25.9mm	8.9mm	13.8mm	10.6mm	18.7mm
4	61.8mm	31.9mm	8.9mm	21.0mm	10.6mm	18.7mm
5S	51.1mm	27.5mm	9.7mm	14.3mm	11.0mm	19.6mm
5	65.5mm	34.0mm	9.7mm	21.8mm	11.0mm	19.6mm
6	69.3mm	36.1mm	10.0mm	23.2mm	11.6mm	20.3mm
7	72.8mm	38.5mm	10.7mm	23.6mm	12.2mm	21.2mm





Regular stem

	Quantity	Description	Catalog #
Lateral	1 Box	1 each, size 7-0	426-0070
	1 Box	1 each, size 6-0	426-0060
	1 Box	1 each, size 5-0	426-0050
	1 Box	1 each, size 4-0	426-0040
	1 Box	1 each, size 3-0	426-0030
	1 Box	1 each, size 2-0	426-0020
Regular	1 Box	1 each, size 0 with grommets	G426-0010
	1 Box	1 each, size 1 with grommets	G426-0001
	1 Box	1 each, size 2 with grommets	G426-0002
	1 Box	1 each, size 3 with grommets	G426-0003
	1 Box	1 each, size 4 with grommets	G426-0004
	1 Box	1 each, size 5 with grommets	G426-0005
	1 Box	1 each, size 6	426-0006
	1 Box	1 each, size 7	426-0007
	1 sizing set	1 each, implant sizes: 0, 2-0, 3-0, 4-0, 5-0, 6-0, 7-0 for lateral toes, numerically marked, color coded (non-sterile) **Not for implantation**	436-0002
	1 sizing set	1 each, implant sizes: 1, 2, 3, 4, 5, 6, 7 for the great toes, numerically marked, color blue (non-sterile) **Not for implantation**	436-0001

Small stem

Quantity	Description	Catalog #
1 Box	1 each, size 0S with grommets	G426-0110
1 Box	1 each, size 1S with grommets	G426-0101
1 Box	1 each, size 2S with grommets	G426-0102
1 Box	1 each, size 3S with grommets	G426-0103
1 Box	1 each, size 4S with grommets	G426-0104
1 Box	1 each, size 5S with grommets	G426-0105
1 sizing set	1 each, implant sizes: 05, 15, 25, 35, 45, 55, for the great toe, numerically marked, color coded (non-sterile) **Not for implantation**	436-0100

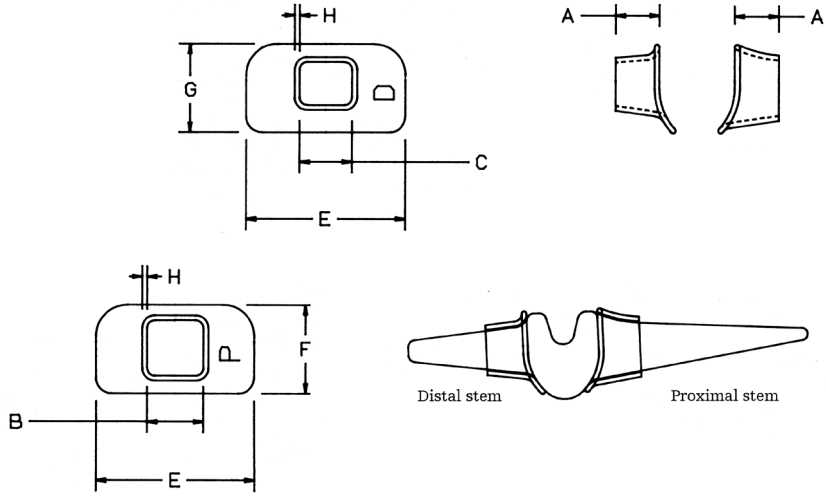
NOTICE

Sizes 0 through 7-0 are most often used for the lateral metatarsophalangeal joints and sizes 0S and 0 through 7 for the great toe.

Toe grommet dimensions

Size/ dimension	A	B	C	E	F	G	H
0S	4.1	5.0	4.7	14.8	8.1	8.1	0.5
1S	4.3	5.3	5.1	15.4	8.5	8.5	0.5
2S	4.5	5.7	5.3	16.1	9.0	9.0	0.5
3S	4.6	6.1	5.6	16.8	9.7	9.7	0.5
4S	4.8	6.6	6.0	17.7	10.2	10.2	0.5
5S	4.9	7.0	6.4	18.4	10.7	10.7	0.5
0	4.1	5.9	5.6	14.6	8.5	8.1	0.5
1	4.3	6.2	5.9	15.2	9.0	8.5	0.5
2	4.5	6.8	6.3	15.8	9.3	9.1	0.5
3	4.6	7.3	6.7	16.6	10.6	9.8	0.5
4	4.8	7.8	7.2	17.4	10.6	10.3	0.5
5	4.9	8.4	7.7	18.3	10.9	10.8	0.5

All dimensions are mm



Typical placement of Swanson Grommet on Swanson Flexible Hinge Toe Implant

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Foot & Ankle

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for cleaning and sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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