



OCT 29 1996

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Director, Office of Device Evaluation (HFZ-400)  
Center for Devices and Radiological Health (CDRH)

Premarket Approval of Surgical Dynamics, a division of United States Surgical Corporation  
Ray Threaded Fusion Cage (TFC)<sup>TM</sup> - ACTION

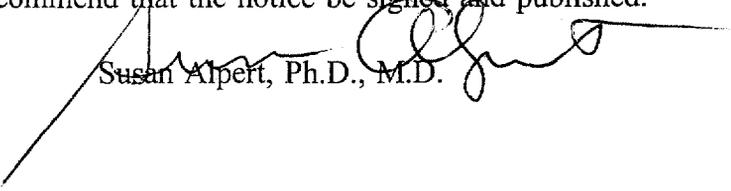
The Director, CDRH  
ORA \_\_\_\_\_

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

- (1) a premarket approval order for the above referenced medical device (Tab B); and
- (2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

  
Susan Alpert, Ph.D., M.D.

Attachments

Tab A - Notice

Tab B - Order

Tab C - S & E Summary

DECISION

Approved \_\_\_\_ Disapproved \_\_\_\_ Date \_\_\_\_\_

Prepared by S.Niver, CDRH, HFZ-410, 9/12/96, 594-2036

Prepared by M.Melkerson, CDRH, HFZ-410, 9/12/96, 594-2036

**DRAFT**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

[DOCKET NO. \_\_\_\_\_]

Surgical Dynamics, a division of United States Surgical Corporation; PREMARKET APPROVAL OF Ray Threaded Fusion Cage (TFC)<sup>™</sup> with instrumentation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Surgical Dynamics, a division of United States Surgical Corporation, Norwalk, CT, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Ray Threaded Fusion Cage (TFC)<sup>™</sup> with instrumentation. After reviewing the recommendation of the Orthopedic and Rehabilitation Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on \_\_\_\_\_, of the approval of the application.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., Rm. 1-23, Rockville, MD 20857.

## FOR FURTHER INFORMATION CONTACT:

Ms. Samie Niver,  
Center for Devices and Radiological Health (HFZ-410),  
Food and Drug Administration,  
9200 Corporate Blvd.,  
Rockville, MD 20850,  
301-594-2036.

SUPPLEMENTARY INFORMATION: On June 14, 1995, Surgical Dynamics, a division of United States Surgical Corporation, Norwalk, CT 06856, submitted to CDRH an application for premarket approval of the Ray Threaded Fusion Cage (TFC)<sup>™</sup> with instrumentation.

This device is an intervertebral body fusion device. It is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The Ray TFC<sup>™</sup> is to be implanted via an open posterior surgical approach.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have experienced approximately six months of non-operative therapy.

On May 23, 1996, the Orthopedic and Rehabilitation Devices Panel, an FDA advisory panel, reviewed and recommended approval of the application.

On \_\_\_\_\_, CDRH approved the application by a letter to the applicant from the Director of the Office of Device

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Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

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### Opportunity for Administrative Review

Section 515(d)(3) of the act, (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.



Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

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This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: \_\_\_\_\_.

\_\_\_\_\_



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Jonathan Gilbert  
Manager, Regulatory Affairs  
United States Surgical Corporation  
150 Glover Avenue  
Norwalk, Connecticut 06856

OCT 29 1996

Re: P950019  
Ray Threaded Fusion Cage (TFC)<sup>TM</sup> with instrumentation  
Filed: June 14, 1995  
Amended: A1 - July 12, 1995; A2 - October 16, 1996; A3 - January 11, 1996; A4 - February 8, 1996; A5 - February 16, 1996; A6 - March 5, 1996; A7 - March 18, 1996; A8 - April 1, 1996; A9 - April 8, 1996; A10 - April 5, 1996; A11 - April 5, 1996; A12 - April 15, 1996; A13 - April 19, 1996; A14 - April 22, 1996; A15 - April 26, 1996; A16 - April 29, 1996; A17 - May 1, 1996; A18 - May 6, 1996; A19 - May 6, 1996; A20 - July 23, 1996; A21 - July 30, 1996; A22 - July 31, 1996; A23 - August 21, 1996; and A24 - September 12, 1996.

Dear Mr. Gilbert:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Ray Threaded Fusion Cage (TFC)<sup>TM</sup> with instrumentation. The device is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The Ray TFC<sup>TM</sup> is to be implanted via an open posterior approach.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative therapy.

We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed) and the following condition that you provide updated promotional and advertising materials in your annual reports. You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

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In addition to the post-approval requirements in the enclosure, the post-approval reports must include the following information:

1. In order to assess the long-term performance of the Ray™ TFC, please conduct a post-approval study to obtain a total of 6 years of postoperative data from a minimum of 100 patients. These outcomes should be submitted to the FDA as part of your annual report. As stated in your PMA amendment received by FDA on September 12, 1996, your post-approval study will incorporate the following elements:
  - a. inclusion of all patients who have already been implanted with the Ray TFC™ as part of the original IDE study. With an approximate 10% loss of patients to follow-up per each of the remaining four years, this should yield a minimum of 100 patients;
  - b. collection of the following information biennially for each patient (because the designated patient population has already reached the two-year time point, patients will be evaluated at his/her 4 and 6-year time points):
    - (1) a description of any surgical interventions which include reoperations, removals, revisions, and supplemental fixations;
    - (2) radiographic assessment of fusion using the same criteria employed in the original IDE study;
    - (3) clinical assessment of pain and function using the Prolo Scale employed in the original IDE study;
  - c. use of following mechanisms to inform the patient of the post-approval study and to better assure an adequate number of patients are available at the completion of the study:
    - (1) patient agreement to participate in the post-approval study by patient signing Patient Letter of Agreement;
    - (2) coverage of expenses for the two remaining examinations; and
  - d. annual assessment of physician compliance with the study.
2. Because of the unknown long-term device performance, particularly the resulting bony fusion characteristics, please conduct a post-approval study that focusses on the retrieval analyses of any Ray TFC™ that is implanted and subsequently removed. This post-approval study is not limited to the patient population described in item 1 above. Histological information (e.g., bony ingrowth quality, bone quantity, response to potential wear debris, etc.) and metallurgical information (e.g., metal wear, deformation, cracking, corrosion, etc.) should be collected and reported in the annual reports. This post-approval study should continue for the duration of the study described in item 1 above.

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Please note that the data obtained in these post-approval studies must be reflected in the labeling (via a PMA supplement) when they are completed.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

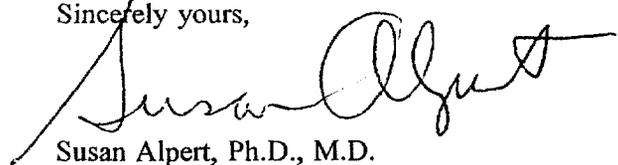
You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling (i.e., package labels, package insert, patient information brochure, and surgical technique manual) in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Ms. Samie Niver at (301) 594-2036.

Sincerely yours,



Susan Alpert, Ph.D., M.D.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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## SUMMARY OF SAFETY AND EFFECTIVENESS

### I. GENERAL INFORMATION

DEVICE GENERIC NAME: Intervertebral Body Fusion Device

DEVICE TRADE NAME: Ray Threaded Fusion Cage (TFC)<sup>TM</sup>

APPLICANT'S NAME: Surgical Dynamics, Inc.  
division of United States Surgical Corporation  
111 Glover Avenue  
Norwalk, CT 06856

PREMARKET APPROVAL (PMA)  
APPLICATION NUMBER: P950019

DATE OF PANEL  
RECOMMENDATION: May 23, 1996

DATE OF NOTICE OF APPROVAL  
TO THE APPLICANT: October 29, 1996

### II. INDICATIONS FOR USE

The Ray TFC<sup>TM</sup> is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The Ray TFC<sup>TM</sup> is to be implanted via an open posterior approach.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative therapy.

### III. DEVICE DESCRIPTION

The Ray TFC<sup>TM</sup> is a hollow, threaded cylinder available in eight sizes. The sizes (diameter x length) are: 12mm x 21mm; 12mm x 26mm; 14mm x 21mm; 14mm x 26mm; 16mm x 21mm; 16mm x 26mm; 18mm x 21mm; and 18mm x 26mm. Each device has external 60° threads with flat crests and roots to allow for primary fixation into a pre-tapped intervertebral cavity. The device has multiple small transverse holes to enhance bony ingrowth. The Ray TFC<sup>TM</sup> is used with anterior and posterior end caps which are available in corresponding diameters of 12mm, 14mm, 16mm, and 18mm.

The Ray TFC<sup>TM</sup> is manufactured from titanium 6Al-4V (extra low interstitial) alloy which conforms to American Society Testing and Materials (ASTM) F136-92. The anterior and posterior end caps are manufactured from ultra-high molecular weight polyethylene

(UHMWPe) which conforms to ASTM F648-84. The Ray TFC™ and end caps are provided sterile.

The Ray TFC™ and end caps are implanted using a defined set of instruments which are available in two categories: size specific and universal. The size specific instruments, which correspond to the diameter of the Ray TFC™, include the following: tang retractor; vertebral drill; vertebral tap; and cage insertion instrument. The universal instruments, which are used regardless of the diameter of the Ray TFC™, include the following: T-handle, end cap insertion instrument, end cap removal instrument; bone packing instrument; impactor cap (tang retractor cap); small/large ganglion retractors; and chisel. All instruments are manufactured from stainless steel which conforms to ASTM F899-94. All instruments are provided nonsterile and must be sterilized prior to use or reuse.

#### **IV. CONTRAINDICATIONS**

The Ray TFC™ should not be implanted in patients with an active infection at the operative site.

#### **V. WARNINGS**

Implantation of a single cage per involved level is not recommended. The implantation of a single cage has been associated with cage fracture.

#### **VI. PRECAUTIONS**

Prior to use, the physician should be trained in the surgical procedure recommended for the use of this device.

Safety and effectiveness have not been established for patients with the following conditions: previous fusion attempt at the involved level(s); spondylolisthesis greater than Grade I; three or more levels to be fused; concomitant conditions requiring steroids; systemic or terminal illness; active drug abuse; pregnancy; gross obesity; or significant loss of quantity or quality of vertebral bone stock usually due to osteoporosis.

The Ray TFC™ and end caps are packaged sterile. Do not use if outer package is opened or damaged. Single use only. Do not re-use. Do not resterilize.

Avoid exposure to freezing temperatures, as this could adversely affect the polyethylene end caps.

Instruments for implantation of the Ray TFC™ and end caps are provided non-sterile and must be sterilized prior to use.

## VII. ALTERNATIVE PRACTICES AND PROCEDURES

Nonoperative alternative treatments may include, but are not limited to, physical therapy, medications, braces, chiropractic care, or exercise programs. In addition, there are alternative spinal fusion techniques. These include, but are not limited to, posterior lumbar interbody fusion (PLIF) procedures without instrumentation, anterior lumbar interbody fusion (ALIF) procedures without instrumentation, combined anterior and posterolateral (360°) fusion procedures, anterior/anterolateral spinal systems (e.g., plate and screw systems), or posterior spinal systems (e.g., hook and rod systems).

## VIII. POTENTIAL ADVERSE EFFECTS

From the investigational device exemption (IDE) G910006, a total of 236 patients were evaluated for adverse events with the Ray TFC™. The adverse events (complications) were stratified into operative and postoperative categories.

The operative complications are presented in Table 1. The rates represent the incidence rates (i.e., number of occurrences of a particular complication divided by the total number of patients enrolled in the study).

Table 1 - Operative Complications

Complication	Rate
dural tear	9.3% (22/236)
instrument malfunctions <sup>1</sup>	5.1% (12/236)
improper device placement	4.2% (10/236)
hemorrhage	2.1% (5/236)
neural structure injury	0.8% (2/236)
incorrect level	0.4% (1/236)

<sup>1</sup>The instruments have since been redesigned with the intent to simplify their use and to address the reported malfunctions.

The postoperative complications are presented in Table 2. Wound infections, urinary retentions, cerebral spinal fluid (CSF) leakages, soft tissue hematomas, premature ejaculation, malposition, and pneumothorax occurred in the early postoperative time frame and were transient. One patient died of causes unrelated to the device or procedure late in the study.

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Table 2 - Postoperative Complications

Complication	Rate
pain, <i>unresolved pain at 24 months</i>	11.0% (26/236) 3.0% (7/236)
neurological deficit <i>unresolved deficit at 24 months</i>	4.7% (11/236) 2.5% (6/236)
surgical interventions <sup>1</sup>	3.4% (8/236)
wound infection	2.5% (6/236)
soft tissue hematoma	1.3% (3/236)
CSF leakage	1.3% (3/236)
urinary retention	0.8% (2/236)
ileus	0.4% (1/236)
device breakage	0.4% (1/236)
epidural fibrosis	0.4% (1/236)
premature ejaculation	0.4% (1/236)
pneumothorax	0.4% (1/236)
death (unrelated to device/procedure)	0.4% (1/236)

<sup>1</sup>includes 3 revisions, 1 removal, 0 reoperations, and 4 supplemental fixations (see definitions below)

A **revision** is a procedure which adjusts or in any way modifies the original implant configuration (e.g., adjusting position of original configuration, removal with replacement of component). A **removal** is a procedure which removes one or more components of the original implant configuration without replacement of any components. A **reoperation** is a procedure which involves any surgical procedure at the involved level(s) which does not remove, modify, or add any components. A **supplemental fixation** is a procedure in which additional instrumentation not approved as part of the protocol is placed. This may include supplemental placement of a rod/screw system or a plate/screw system.

Patients who had surgical interventions in this study have already been accounted for in the other complications identified in Tables 1 and 2 above. The complications that led to these surgical interventions include the following. Three patients underwent revisions: 1) urinary problems led to one device being removed and reimplanted hours postoperatively; 2) too small of a device led to it being removed and replaced with a larger device the same day as the original surgery; and 3) improper device placement led to the

device being repositioned 40 days postoperatively. One patient underwent a device removal three years postoperatively due to neurological deficit and pain. Four patients underwent supplemental fixations to have pedicle screw systems added at 240, 329, 362, and 827 days postoperatively, respectively.

**IX. MARKETING HISTORY**

The Ray TFC™ has been marketed in approximately 16 international countries. It has not been withdrawn from marketing for any reason relating to its safety or effectiveness.

**X. SUMMARY OF PRECLINICAL STUDIES**

Nonclinical tests were conducted to characterize the mechanical properties of the Ray TFC™.

**A. Static Superior-Inferior Compression Testing**

The first set of static compression tests of the Ray TFC™ was performed using wood blocks as the vertebral model. Although yield strength (load) is typically defined as stress (load) corresponding to 0.2% of permanent deformation, it was defined as 0.001 inches of permanent deformation, a more conservative estimate of yield strength, in this set of static tests. Five samples of each cage were tested. Except for the 14mm cage, which had one outlier that was not included in the average results, all data are included in the average. The average static yield strengths were:

Ray TFC™ Size	Static Yield Strength
14mm x 21mm	2167 ± 142 N (487 ± 32 lbs)
16mm x 21mm	2114 ± 138 N (475 ± 31 lbs)
16mm x 26mm	2203 ± 93 N (495 ± 21 lbs)
18mm x 26mm	2826 ± 312 N (635 ± 70 lbs)

A second set of static compression tests was performed using steel blocks as the vertebral model because of the amount of deformation that the oak blocks underwent during compression. Additionally, the static yield load was redefined as 0.2% of permanent deformation. Five samples of each cage were tested. The average static yield strengths were:

Ray TFC™ Size	Static Yield Strength
12mm x 26mm	13617 ± 2648 N (3060 ± 595 lbs)

16mm x 26mm	10458 ± 1847 N (2350 ± 415 lbs)
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The device's compressive strength greatly exceeds the compressive strength of bone which is estimated to be approximately 1500 N (337 lbs).

#### B. Fatigue Testing

Fatigue testing was performed on the Ray TFC™ using oak blocks as vertebral models. All of the tests involved a single cage construct with the end caps in place. There were two sets of fatigue tests, both involved loading the device constructs at 4 Hz. In the first set of tests, the loads were applied without preloading until 10 million cycles were reached or failure (defined as a microfracture). In the second set of tests, the cages which showed microfractures prior to 5 million cycles in the first set of tests were retested past 7 million cycles. This was to show that the devices with microfractures could still be capable of carrying the applied loads.

A total of 38 samples (6-17 samples per cage diameter) were tested. This includes the four (4) cages that were retested. The 12mm, 14mm, and 16mm Ray TFC™s all had fatigue strengths (i.e., endurance limits) of approximately 1335 N (300 lbs) at cycles ranging from five (5) million to over 15 million. The 18mm Ray TFC™ had a fatigue strength of approximately 890 N (200 lbs) at cycles ranging from eight (8) million to over 15 million. Five (5) million cycles typically represents the number of loading cycles a device might experience within two years. This assumes moderate loading and the device's goal of stabilizing until fusion occurs within those two years. Because of the way the fatigue testing was performed, the endurance limits for each cage size at five (5) million cycles could not be derived. It is expected that if the device was tested in that manner, the endurance limits at five (5) million cycles would be greater than those reported above.

After testing, there were a total of eight (8) of 38 cages with microfractures, but all of the cages stayed intact and were capable of withstanding the applied loading. There were no reported end cap dislodgments. Although the Ray TFC™ can be expected to withstand anticipated physiologic fatigue loads, the Ray TFC™ should be implanted as a pair based on the resulting fatigue strengths. This is reflected in the Warnings section of the labeling.

#### C. Static Closure (End Cap) Testing

Static loads were applied to the anterior and posterior end caps to determine the loads required to insert or extract the end caps from the Ray TFC™. Five samples were tested for each Ray TFC™ and end cap construct. The average insertion and extraction loads were:

End Cap	Insertion Force	Extraction Force
14mm (posterior)	55 N (12 lbs)	58 N (13 lbs)
16mm (posterior)	68 N (15 lbs)	97 N (22 lbs)
18mm (posterior)	65 N (15 lbs)	112 N (25 lbs)
14mm (anterior)	not tested	85 N (19 lbs)
16mm (anterior)	not tested	212 N (48 lbs)
18mm (anterior)	not tested	138 N (31 lbs)

Based on the expected minimal loading on the end caps, the end caps should not become dislodged from the Ray TFC™.

#### D. **Expulsion Testing**

The loads required to dislodge a Ray TFC™ when implanted between two calf vertebrae were measured. Two calf vertebrae and the adjacent disc were potted in cement. Pull-out forces up to 500 lbs or until a displacement of 0.01 inch were applied to the device. Five samples of each were tested. The average pull-out strengths were:

Ray TFC™ Size	Pull-Out Strength
14mm x 21mm	2225 N (500 lbs) - no failure
16mm x 21mm	2198 N (494 lbs)
18mm x 26mm	2092 N (470 lbs)

Loading of this type and magnitude are not expected in the spine where the Ray TFC™ is to be placed. Therefore, expulsion of the Ray TFC™ is not expected with proper sizing and placement.

## XI. **SUMMARY OF CLINICAL INVESTIGATIONS**

A clinical study of the Ray TFC™ was conducted in accordance with an approved IDE G910006.

#### A. **Objective**

The objective of the study was to determine the safety and effectiveness of the Ray TFC™ in stabilizing and fusing the diseased level(s) when compared to literature controls.

## **B. Inclusion and Exclusion Criteria**

The inclusion criteria were males and females at least 18 years of age with symptomatic DDD at 1 or 2 levels from L2 to S1. Symptomatic DDD was defined as one or more of the following conditions: low back pain with or without sciatica; pain reproduction during provocative discography; annular degeneration; disc herniation; loss of disc height; and/or osteophytes. The inclusion criteria involved primary and secondary surgery but no previous PLIF at the involved level(s). Note that based on Panel input, the definition for DDD was refined to that reflected in Section II above, Indications for Use.

The exclusion criteria were as follows: anatomic anomalies of the bone to be fused; previous fusion at the same level; spondylolisthesis greater than Grade I; need for three or more levels fused; concomitant conditions requiring steroids; systemic or terminal illness; active drug abuse; significant endplate sclerosis at the diseased level; active infection; DDD of the cervical or thoracic regions; and pregnancy.

All patients were implanted via a posterior surgical approach. Autogenous bone graft was packed into the Ray TFC™ devices after implantation.

## **C. Patient Population and Demographics**

The Ray TFC™ study is comprised of 62% (147/236) males and 38% (89/236) females. The mean age at time of study enrollment was 41.4 years with a range of 19 to 80 years. 40% (95/236) of the patients were on worker's compensation. 7% (17/236) were involved in ongoing litigation. 27% (63/236) were smokers and 45% (106/236) had prior back surgery.

All 236 patients enrolled in the Ray TFC™ study had a diagnosis of DDD. These patients presented at least one or more of the following preoperative DDD diagnostic criteria: 98% (232/236) low back pain; 39% (92/236) pain reproduction upon discography; 66% (155/236) herniated disc; 59% (139/236) degenerated annulus; 44% (104/236) disrupted annulus; 47% (112/236) disc height loss; and 17% (39/236) osteophytes.

A total of 298 levels were implanted in 236 patients. The distribution of the levels were: 0% at L2-L3; 6% (17/298) at L3-L4; 43% (128/298) at L4-L5; 1% (3/298) at L5-L6; and 50% (150/298) at L5-S1. Of the 236 patients, 74% (175/236) had one-level fusions, 25% (60/236) had two-level fusions, and <1% (1/236) had three-level fusions. There were 10 single cages and 288 pairs of cages implanted for a total of 586 cages implanted.

## **D. Evaluation Schedule**

Patients were evaluated preoperatively, immediately postoperatively (i.e., at hospital discharge), at 6 weeks, 3 months, 6 months, 12 months, 18 months (optional), 24 months, and biennially thereafter until the last patient had his/her two-year evaluation.

Radiographic studies were conducted at 6 months, 12 months, and 24 months postoperatively. Optional films were taken at 18 months.

#### **E. Patient Accountability**

A total of 236 patients were enrolled at 10 investigational sites in the United States by 13 investigators. As of March, 1996, all patients but the one unrelated death had reached his/her two-year postoperative time point. Follow-up evaluations, which included an assessment of fusion, pain, function, and muscle strength, were performed on 209 of 235 patients (89%) at the two-year time point. Complete follow-up evaluations (i.e., measurement of each of the four major outcome parameters) were performed on 199 of these 209 patients (95%).

#### **F. Study Design and Analyses**

##### **1. Literature Study Control**

Literature controls were employed in this study. Outcomes of patients implanted with Ray TFC™s were compared to outcomes of patients who received PLIFs. Literature references were deemed acceptable as controls if the patients were considered to have DDD; this group may or may not have had spondylolisthesis of Grade I or less. This differs from the Ray TFC™ group in which all patients had back pain due to DDD and had no greater than Grade I spondylolisthesis.

The literature controls used in this study had many differences relative to the Ray TFC™ population with respect to the indication for use, the method by which DDD was defined, the number of levels fused, the age of the patients, the types of outcome criteria assessed, the method of outcome assessment, the definitions for successful outcome, the duration and nature of follow-up, the incidence of previous back surgery at the same level, and whether the patients were affected by more than two psychological/behavioral risk factors (e.g., alcoholism, drug abuse).

Use of a literature control group was common at the time of the submission of this study, although it is now recognized as less desirable than a randomized, concurrent control study. The advantages of using a randomized, concurrent control reflects the disadvantages of literature controls. In general, in a randomized, concurrent control study, potential bias is eliminated or at least reduced, unknown or known baseline factors tend to be balanced between the two groups, the statistical properties of hypothetical tests are improved, time trends are controlled because of concurrency, and the results tend to be more successfully convincing.

##### **2. Retrospective Study Control**

In addition to using literature controls, the use of a retrospective control group was proposed. This proposed additional control group consisted of retrospective data from 187 patients who had PLIFs without instrumentation for the treatment of DDD. The data were taken from five of the investigators involved in the original IDE study. 51% (95/187) of the patients had reached the one-year postoperative time point and 19% (36/187) had reached the two-year postoperative time point. As with the literature control, the patient population of the retrospective control group had many differences relative to the Ray TFC™ population. The retrospective control data were not used in comparing safety and effectiveness information based on the major differences between the two patient populations that could lead to invalid conclusions. Some of the main reasons for not considering this retrospective control group were that 82% of the retrospective group received allograft instead of autograft material, only 19% of the patients have two years of postoperative data, there was a retrospective determination of the Prolo Scale (i.e., pain and function scores), the subjective nature of the fusion assessments, and the patient selection bias.

### 3. Data Pooling

There were two device configurations involved in the IDE study, a hydroxylapatite (HA) coated Ray TFC™ and a non-HA coated Ray TFC™. The HA coating had no statistically different effect on the subject patient population through longitudinal analyses (using Generalized Estimating Equation (GEE) model). Therefore, the HA and non-HA data were pooled. As reflected in Section III above, Device Description, only the non-HA coated Ray TFC™ is to be marketed.

Pooling the data between investigational sites was justified based on statistical analyses using the chi-squared test. Pooling the data between binary stratified groups (e.g., 1-level versus 2-levels, smokers versus nonsmokers) was also justified based on longitudinal analyses using GEE models.

### G. Effectiveness Analyses

The effectiveness variables included an assessment of fusion at the involved level(s), pain, function, and muscle strength. In some cases, only partial data were available (i.e., not all of the four outcome measures were obtained for all patients at all follow-up points). In these cases, all available outcomes for fusion, pain, function, and muscle strength were summarized in these analyses. Therefore, the number of patients included in the assessment of the four major outcomes varies slightly due to missing data. Because all of the patients had reached his/her two-year postoperative time point, the effectiveness analyses involved the 24 month time point.

### H. Effectiveness Analysis - Fusion

Successful fusion was defined as no motion on a flexion/extension series of x-rays at the involved level(s), no halo around the implant, no bone sclerosis around the implant, and increased or maintained bony density within the implant. All four of the criteria had to be met for successful fusion. In cases where two levels were implanted, both levels must have been fused in order for that patient to be considered fused. Both the IDE investigator and an independent radiologist reviewed the films. The independent radiologist reported fusion in all of the films that were available for review. A "nonfusion" determination by an investigator outweighed a "fusion" determination by the independent radiologist. The successful fusion rate at 24 months was 92% (183/200).

**I. Effectiveness Analysis - Pain**

Pain was measured on the Prolo Scale. The "functional" grade of the Prolo Scale ranks the pain responses and effect of pain on activities of daily living. This portion of the Prolo Scale is a 5-point scale where F1 = total incapacitation, F2 = mild to moderate level of low back pain and/or sciatica, F3 = low level of pain but able to perform all activities except sports (use of occasional prescription analgesics), F4 = no pain but has one or more recurrences of low back pain or sciatic (occasional over-the-counter analgesics), and F5 = complete recovery and able to perform all previous sports activities.

The distribution of pain scores preoperatively and at 24 months is shown in Table 3 below.

Table 3 - Distribution of Pain Scores

Pain Level	Preoperative Rate	24 Month Rate
F5 (best)	0%	29% (61/209)
F4	1% (3/236)	26% (54/209)
F3	8% (18/236)	22% (45/209)
F2	88% (208/236)	23% (49/209)
F1 (worst)	3% (7/236)	0%

All patients experiencing an improvement by at least one level in the pain score relative to their preoperative score were considered to have a successful result in terms of the pain outcome measure. The successful pain rate at 24 months was 76% (158/209).

It is important to distinguish between patients with a successful pain outcome and the amount of pain experienced by patients after implantation with the Ray TFC™. A successful outcome did not necessarily mean that a patient experienced no pain; instead, it means that there was at least one level of improvement.

**J. Effectiveness Analysis - Function**

Like the pain parameter, function was also measured on the Prolo Scale. The "economic" grade of the Prolo Scale expresses the patient's capacity for gainful employment or alternative comparable pursuits (e.g., housework, retirement activities, etc.). This portion of the Prolo Scale is a 5-point scale where E1 = complete invalid; E2 = no gainful occupation (capable of independent locomotion and self care, but unable to hold job, perform housework, attend school, or continue retirement activities); E3 = able to work (attend school, participate in retirement activities, do housework) but not at previous occupation or level of activity); E4 = working at previous occupation on part-time or modified status (attending school, doing housework, performing retirement activities); and E5 = able to work at previous occupation without any restrictions (attend school, do housework, perform retirement activities).

The distribution of function scores preoperatively and at 24 months is shown in Table 4 below.

Table 4 - Distribution of Function Scores

Function Level	Preoperative Rate	24 Month Rate
E5 (best)	3% (7/236)	43% (90/209)
E4	9% (21/236)	23% (48/209)
E3	26% (62/236)	18% (38/209)
E2	61% (143/236)	16% (33/209)
E1 (worst)	1% (3/236)	0%

All patients maintaining or experiencing an improvement by at least one point in the function score relative to their preoperative score were considered to have a successful result in terms of the function outcome measure. The successful function rate at 24 months was 96% (200/209).

#### K. Effectiveness Analysis - Muscle Strength

Muscle strength was evaluated bilaterally at eight sites: hip flexion, hip extension, hip abduction, hip adduction, knee flexion, knee extension, ankle plantarflexion, and ankle dorsiflexion. Each of the sites was measured on a 6-point scale ranging from 0 (no evidence of contractility) to 5 (complete motion against gravity, full resistance).

The average mean strength score was  $4.94 \pm 0.27$  preoperatively and  $4.99 \pm 0.05$  at 24 months. Maintenance or improvement in mean muscle strength score was required in order for the patient to be considered a success. The successful muscle strength rate at 24 months was 95% (197/208).

#### L. Effectiveness Analysis - Disc Height

In addition to the measuring the four major effectiveness variables, the anterior and posterior disc height spaces were measured. The mean anterior disc height was  $11.2 \pm 4.4$ mm preoperatively and  $11.3 \pm 3.9$ mm at 24 months. There was no significant change in the anterior disc height space. The mean posterior disc height was  $6.1 \pm 2.5$ mm preoperatively and  $7.5 \pm 3.0$ mm at 24 months. There was a significant increase in the posterior disc height space.

#### M. Safety Analysis

Safety analyses included all patients regardless of the completeness of their follow-up data. Safety was assessed through physical examinations, x-rays, and by questioning of all patients enrolled in the study. For a summary of the safety data, please see Tables 1 and 2 in Section VIII above, Potential Adverse Effects.

From the complications previously identified in Tables 1 or 2, there are some postoperative complications that are considered to be clinically significant because they are either generally irreversible or require major surgical intervention for resolution. For this reason, the rates of these clinically significant complications are compared between the Ray TFC™ group and the literature controls. The rates shown in Table 5 below are the number patients with the clinically significant complication divided by the total number of patients in the study. Again, the complications for the Ray TFC™ group have already been identified above in Tables 1 or 2.

Table 5 - Clinically Significant Postoperative Complications

Complication	Ray TFC™ Rate	Literature Rate <sup>1</sup>
surgical interventions <sup>2</sup>	3.4%	0.5% - 11.0%
unresolved pain	3.0%	1.6% - 4.2% <sup>3</sup>
unresolved neurological deficit	2.5%	0% - 5.0% <sup>4</sup>
CSF leak	1.3%	0.5% - 3.0%
serious wound infection	0.8%	0% - 5.6%
ileus	0.4%	0.3%
death <sup>5</sup>	0.4%	0% - 1.1%
graft/device breakage	0.4%	1%
graft/device extrusion or migration	0%	0% - 7%
pulmonary embolus	0%	0.2% - 2.2%

gastro-intestinal (GI) bleeding	0%	0.3%
myocardial infarction	0%	0.4% - 2.9%
thrombophlebitis	0%	0%-4.8%
nephritis	0%	6.0%

<sup>1</sup>The literature rates were based on only the articles that reported or referenced the complication. The complication rates without a range of literature rates were reported only in one article. The literature sample sizes ranged from 13 to 750 patients.

<sup>2</sup>Surgical interventions includes any revisions, removals, reoperations, and supplemental fixations.

<sup>3</sup>It was not possible to always determine whether the pain reported in literature was unresolved or serious pain.

<sup>4</sup>It was not possible to always determine whether the neurological deficits reported in literature were unresolved.

<sup>5</sup>The death reported in the study was not related to device or procedure. It was not possible to always determine whether the deaths reported in literature were device or procedure related.

#### N. Study Success / Statistical Differences

To be considered an overall study success, the patient must have met each of the following four criteria: 1) fusion of the involved level(s); 2) improvement in pain; 3) maintenance or improvement in function; and 4) maintenance or improvement in muscle strength. The success rates at 24 months for each individual outcome parameter as well as overall success based on all four parameters are shown in Table 6. Note that the number of patients with data available differs slightly for each outcome success criteria based on the study follow-up.

Table 6 - Study Success Rates at 24 Months

Success Criteria	Rate
Fusion Rate	92% (183/200)
Pain Improvement	76% (158/209)
Function Maintenance or Improvement	96% (200/209)
Muscle Strength Maintenance or Improvement	95% (197/208)

Overall Success (met all 4 above)	64% (128/199)
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Because of the many differences between the control groups and the Ray TFC™ group, the longitudinal analyses performed on the Ray TFC™ patient population was extremely important in the assessment of the safety and effectiveness of the Ray TFC™ device. The longitudinal analyses (using Generalized Estimating Equation (GEE) model) showed that the outcomes did not worsen over time. Specifically, the rate of fusion increased with time, the amount of pain decreased with time, and the patient's ability to function increased with time.

From the longitudinal analyses of these clinical data, the following statistical differences were observed up to or at the two-year time point:

- Younger patients had lower levels of pain and higher levels of function than older patients.
- Nonsmokers had lower levels of pain and higher levels of function than smokers.
- Patients with baseline disc herniation had lower levels of pain than those without baseline disc herniation.
- Older patients with L5-S1 involvement had higher levels of pain than older patients with other levels of involvement. In younger patients, there was no significant effect on pain based on level of involvement.
- Patients who had lower baseline function scores showed lower levels of function through the study than those with higher baseline function scores.
- Older patients with L5-S1 involvement had lower levels of function than older patients with other levels of involvement. Additionally, older patients with lower baseline function scores had lower levels of function than older patients with higher baseline function scores. In younger patients, there was no significant effect on function based on level of involvement or baseline function score.
- Patients receiving worker's compensation had higher levels of pain and lower levels of function than those not receiving worker's compensation.

**O. Comparison with Literature Controls**

A total of 13 PLIF literature articles were used as controls; these are identified in Section XVII below, References. The sample sizes reported in these articles ranged from 13 to 750. As previously discussed, these literature controls were often greatly different from the Ray TFC™ population. However, clinical results and complication information were



extracted for purposes of this comparison. Ray TFC™ patients at 24 months follow-up were selected for this comparison.

The fusion rate for the Ray TFC™ was 92% (183/200). The range of fusion rates reported in the PLIF literature controls was 82% to 98%. Fusion results for the Ray TFC™ were better than literature results in 7 of 13 articles and worse in 5 (1 article did not report the fusion rate). The Ray TFC™ was not significantly worse than any literature controls.

The definition of clinical success in the PLIF literature primarily involved an assessment of pain, analgesic use, work status, and activity level. The clinical success rates reported in the PLIF literature controls based on the author's definitions of excellent and good, ranged from 24% to 91%. The clinical success rates reported in the PLIF literature controls based on the author's definitions for excellent, good, and fair, ranged from 60% to 98%. Taking into consideration the same types of measurements, these literature control rates were compared to the following Ray TFC™ clinical rates: 76% (158/209) for pain and 96% (200/209) for function. It cannot be determined if the differences are due to true differences in clinical success, or due to differences in patient population, data collection, or interpretation of methods used to determine success.

The experience in this clinical investigation with the Ray TFC™ compares favorably with literature complication rates for PLIFs. Reported complications for the Ray TFC™ were within the range reported for the literature control groups. This is shown in Table 5 above in Section M, Safety Analysis.

## **XII. SUMMARY OF OTHER CLINICAL INVESTIGATIONS**

Prior to the submission of any IDE, one of the primary investigators for the IDE study implanted prototypes of the Ray TFC™ into 10 patients under the sponsorship of another company. The patients were diagnosed as having DDD requiring posterior lumbar interbody fusion (PLIF). Four of the devices were made from stainless steel and six were made from commercially pure titanium. The report of clinical and radiographic results was essentially incomplete and anecdotal. The fusion rate was reported as 91% at one year and 88% at five years. Complications included a dural tear, CSF leak, and stress cracks in the cages.

## **XIII. CONCLUSIONS DRAWN FROM THE STUDIES**

The nonclinical (i.e., mechanical) and clinical data provide reasonable assurance of the safety and effectiveness of the Ray TFC™ for the treatment of degenerative disc disease (DDD), when used as indicated.

## **XIV. PANEL RECOMMENDATIONS**

The Orthopedic and Rehabilitation Devices Panel met to discuss the application on May

23, 1996. The Panel recommended that the application be approved pending submission to and approval by the Center for Devices and Radiological Health (CDRH) of: a reanalysis of the study outcomes with a revised definition of patient success; modifications to the labeling; creation of a patient information document; development of post-approval studies; additional statistical analyses; and additional sterilization information regarding the end cap. The Panel agreed with FDA's recommendation to define patient success as fusion of involved level(s); improvement in pain; maintenance or improvement in function; maintenance or improvement in muscle strength; and maintenance or improvement in neurological reflexes.

The Panel recommended that the labeling be modified to: (1) limit use to the treatment of patients with DDD where DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by historical and radiographic studies; (2) recommend a minimum of six months of non-operative treatment; (3) report the study's success rates and trends noted in the statistical analyses; (4) require that the device be packed with autograft bone; (5) limit use of the device to fusions involving one or two levels; and (6) include a warning against implantation of a single cage per involved level.

As stated above, the Panel also recommended that two post-approval studies be developed. The first post-approval study is to obtain continued follow-up for a subset of the patients from the IDE study to evaluate the long-term device performance and patient outcomes for a minimum of five years. The second post-approval study is to retrieve and analyze any Ray TFC™ device that was implanted and subsequently removed. The Panel recommended that retrieved implants be analyzed metallurgically and histologically for bone quality/quantity and potential wear debris.

## **XV. CDRH DECISION**

CDRH agreed with each of the Panel's conditions. However, based on the major statistical analyses recommended by the Panel, FDA issued a letter to United States Surgical Corporation on June 20, 1996 advising them that the PMA lacked information needed to complete the review and to determine whether there was reasonable assurance that the device is safe and effective for its intended use. This June 20, 1996 letter included the Panel's recommended conditions of approval as well as required the following information: additional complication information; sterilization information for the instruments; revision of the labeling to incorporate all applicable changes (e.g., indications for use, clinical results, complications); modifications to the surgical technique manual; generation of a surgeon training program; and development of the post-approval studies with specific elements.

In amendments received by FDA on July 23 and August 21, 1996, United States Surgical Corporation submitted the requested information. The company reanalyzed the clinical outcomes using the revised definition of overall patient success (redefined again to be based on only fusion, pain, function, and muscle strength while capturing neurological

information in the complication section), defined the patient population, performed additional statistical analyses, addressed the sterilizations issues for the end cap and instruments, revised the labeling, modified the surgical technique manual, described their surgeon training program, and developed two post-approval studies. The first post-approval study involves the collection of clinical and radiographic data for long term device performance and patient outcomes for an additional four years of follow-up (for a total of six years of postoperative data) on the IDE patient population; the goal is to obtain six years of postoperative data on a minimum of 100 patients. The second post-approval study involves the retrieval assessment of any Ray TFC™ that is implanted and subsequently removed.



Based on the additional information submitted by United States Surgical Corporation, CDRH agreed with the Panel's recommendations that the PMA be approved subject to the conditions above. On August 29, 1996, FDA issued a letter to United States Surgical Corporation advising them that its PMA was approvable based on the conditions listed above. The one deficiency cited in the letter involved revising the surgical technique manual.

In an amendment received by FDA on September 12, 1996, United States Surgical Corporation submitted the required information which included revisions to the labeling and post-approval studies and agreed to the conditions cited in the letter dated August 29, 1996. CDRH determined that, based on the above modifications, the applicant's response was adequate.

FDA inspections completed on September 6 and 25, 1996 and determined the manufacturing facilities to be in compliance with the Good Manufacturing Practices (GMP) regulations.

CDRH issued an approval order on October 29, 1996.

#### **XVI. APPROVAL SPECIFICATIONS**

Directions for Use: See labeling.

Hazards to Health from Use of the Device: See indications, contraindications, warnings, precautions, and adverse events in labeling.

Post-approval Requirements and Restrictions: See approval order.

#### **XVII. REFERENCES FOR CONTROLS**

Branch, C. and Branch, C. Jr., "Posterior Interbody Fusion with the Keystone Graft: Technique and Results," *Surgical Neurology*, 27: 449-454, 1987.

Collis, J., "Totally Disc Replacement: A Modified Posterior Lumbar Interbody Fusion. Report of 750 Cases," *Clinical Orthopaedics and Related Research*, 193: 64-67, 1985.

Hutter, C., "Posterior Intervertebral Body Fusion: A 25-year Study," *Clinical Orthopaedics and Related Research*, 86-96, 1983.

Lin, P., et al., "Posterior Lumbar Interbody Fusion," *Clinical Orthopaedics and Related Research*, 180: 154-168, 1983.

Ma, G., "Posterior Lumbar Interbody Fusion with Specialized Instruments," *Clinical Orthopaedics and Related Research*, 193: 57-63, 1985.

Mitsunaga, M., et al., "Microscopically Assisted Posterior Lumbar Interbody Fusion," *Clinical Orthopaedics and Related Research*, 263: 121-127, 1991.

Prolo, D., et al., "Toward Uniformity in Evaluating Results of Lumbar Spine Operations: A Paradigm Applied to Posterior Lumbar Interbody Fusions," *Spine*, 11(6): 601-606, 1986.

Rish, B., "A Critique of Posterior Interbody Fusion: 12 Years' Experience with 250 Patients," *Surgical Neurology*, 31: 281-289, 1989.

Schechter, N., et al., "Disc Disease Update Painful Internal Disc Derangements of the Lumbosacral Spine: Discographic Diagnosis and Treatment by Posterior Lumbar Interbody Fusion," *Orthopedics*, 14: 447-450, 1991.

Sepulveda, R. and Kant, A., "Chemonucleolysis Failures Treated by PLIF," *Clinical Orthopaedics and Related Research*, 193: 68-74, 1985.

Simmons, J., "Posterior Lumbar Interbody Fusion with Posterior Elements as Chip Grafts," *Clinical Orthopaedics and Related Research*, 193: 85-89, 1985.

Takeda, M., "Experience in Posterior Lumbar Interbody Fusion: Unicortical Versus Bicortical Autologous Grafts," *Clinical Orthopaedics and Related Research*, 193: 120-126, 1985.

Tunturi, T., et al., "Posterior Fusion of the Lumbosacral Spine," *Acta Orthop Scand*, 50: 415-425, 1979.

## Ray Threaded Fusion Cage DRAFT PACKAGE INSERT

Prior to use, the physician should be trained in the surgical procedure recommended for the use of this device.

### **Device Description:**

The Ray Threaded Fusion Cage (TFC) is available in eight sizes, with 4 diameters (12 mm, 14mm, 16 mm and 18 mm) and 2 lengths (21 mm or 26 mm). It is composed of Titanium 6Al-4V (extra low interstitial) alloy which conforms to the American Society for Testing and Materials (ASTM) F136-92. The Ray TFC is used with anterior and posterior end caps which are available in corresponding diameters of 12 mm, 14 mm, 16 mm and 18 mm. The end caps are composed of ultra-high-molecular weight polyethylene (UHMWPE) which conforms to ASTM F648-84.

The Ray TFC and endcaps are implanted using a set of stainless steel instruments which conform to ASTM F899-94. Refer to the Surgical Technique Manual for a full description of these instruments and their cleaning and sterilization instructions.

### **Indications:**

The Ray TFC is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The Ray TFC is to be implanted via an open posterior approach.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative therapy.

### **Contraindications:**

The Ray TFC should not be implanted in patients with an active infection at the operative site.

### **Warnings:**

Implantation of a single cage per involved level is not recommended. The implantation of a single cage has been associated with cage fracture.

### **Precautions:**

- Prior to use, the physician should be trained in the surgical procedure recommended for the use of this device.
- Safety and effectiveness have not been established for patients with the following conditions: previous fusion attempt at the involved level(s), spondylolisthesis greater than Grade I, three or more levels to be fused, concomitant conditions requiring steroids, systemic or terminal illness, active drug abuse, gross obesity, severe osteoporotic conditions and pregnancy.
- The Ray TFC and end caps are packaged sterile. Do not use if the outer package is opened or damaged. Single use only. Do not re-use. Do not resterilize.
- Instruments for implantation of the Ray TFC and end caps are provided non-sterile and must be sterilized prior to use.
- Avoid exposure to freezing temperatures, as this could adversely affect the polyethylene end caps.

B

### Adverse Events:

A 2-year, multi-center clinical study of 236 patients implanted with the Ray TFC was completed. The rates of the complications reported in this study are provided below.

### Operative Complications:

Operative complications are presented in Table 1 below. The rates presented are the number of a particular complication divided by the total number of patients in the study (n=236).

Table 1	Complications	Rate
	dural tear	9.3% (22)
	instrument malfunctions*	5.1% (12)
	improper device placement	4.2% (10)
	hemorrhage	2.1% (5)
	neural structure injury	0.8% (2)
	incorrect level	0.4% (1)

\*the instruments have since been redesigned with the intent to simplify their use and to address the reported malfunctions

### Post Operative Complications:

Post operative complications recorded through 24 months are presented below in Table 2. The rates presented are the number of patients with a particular complication divided by the total number of patients in the study (n=236).

Table 2	Complications	Rate
	pain	11.0% (26)
	<i>unresolved pain at two years</i>	3.0% (7)
	neurological deficit	4.7% (11)
	<i>unresolved neurological deficit at two years</i>	2.5% (6)
	surgical intervention*	3.4% (8)
	wound infection	2.5% (6)
	soft tissue hematoma	1.3% (3)
	CSF leak	1.3% (3)
	urinary retention	0.8% (2)
	ileus	0.4% (1)
	device breakage	0.4% (1)
	death (unrelated to device or procedure)	0.4% (1)
	epidural fibrosis	0.4% (1)
	premature ejaculation	0.4% (1)
	pneumothorax	0.4% (1)

### Notes:

\*surgical intervention includes 3 revisions, 1 removal, 0 reoperations and 4 supplemental fixations

No complications were reported for osteomyelitis, vertebral body fractures, spondylolisthesis, dislocation of device, dislocation of device closure, urinary tract infection, pulmonary embolus, GI bleeding, myocardial infarction, thrombophlebitis or nephritis.

**Clinical Results:**

The following are clinical results of the same multi-center clinical study presented above. The success rates are for overall success as well as for each of the four major individual measures of success. Overall success was defined as fusion at the involved level(s), improvement in pain; maintenance or improvement in function; and maintenance or improvement in muscle strength. Note the actual number of patients with data available differs slightly for each success criteria based on study follow-up.

It should be noted fusion is defined as follows: no motion on superimposition of flexion and extension x-rays, as corroborated by the absence of halo around the implant, the absence of bone sclerosis, and the maintenance or increase in bone density within the cage.

Success Parameters	Success Rates
Overall Success	64%
Fusion Rate	92%
Pain Improvement	76%
Function Maintenance or Improvement	96%
Muscle Strength Maintenance or Improvement	95%

From this clinical study, the following statistical differences were observed up to or at the 2-year time point:

- Younger patients had lower levels of pain and higher levels of function than older patients.
- Nonsmokers had lower levels of pain and higher levels of function than smokers.
- Patients with baseline disc herniation had lower levels of pain than those without baseline disc herniation.
- Older patients with L5-S1 involvement had higher levels of pain than older patients with other levels of involvement. In younger patients, there was no significant effect on pain based on level of involvement.
- Patients who had lower baseline function scores showed lower levels of function through the study than those with higher baseline scores.
- Older patients with L5-S1 involvement had lower levels of function than older patients with other levels of involvement. Additionally, older patients with lower baseline function scores had lower levels of function than older patients with higher baseline function scores. In younger patients, there was no significant effect on function based on level of involvement or baseline function score.

**Caution:**

U.S. federal law restricts this device to sale by or on the order of a physician with appropriate training or experience.

**Device Retrieval Efforts:**

Should it be necessary to remove a Ray TFC, please call Surgical Dynamics, Inc. at the number below to receive manufacturer's instructions regarding data collection, including histopathological, mechanical and adverse event information.

**Ordering information:**

The Ray Threaded Fusion Cage can be ordered from your distributor, or contact Surgical Dynamics at 111 Glover Avenue, Norwalk, CT 06856 USA 800.822.4734 or 203.761.0821

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Surgical Dynamics™  
**Ray TFC™ Device**  
SURGICAL TECHNIQUE MANUAL

**IMPORTANT!**

Prior to use, the physician should be trained in the surgical procedure recommended for the use of this device.

**BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.**

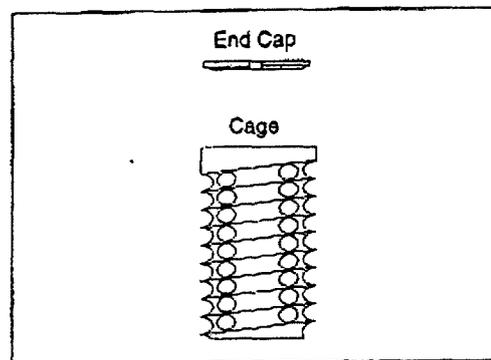
**CAUTION:** U.S. federal law restricts this device to sale by or on the order of a physician with appropriate training or experience.

**INDICATIONS**

Please refer to the Ray TFC™ device package insert for indications, contraindications, precautions, clinical study success criteria and rates, and complications.

**DEVICE DESCRIPTION**

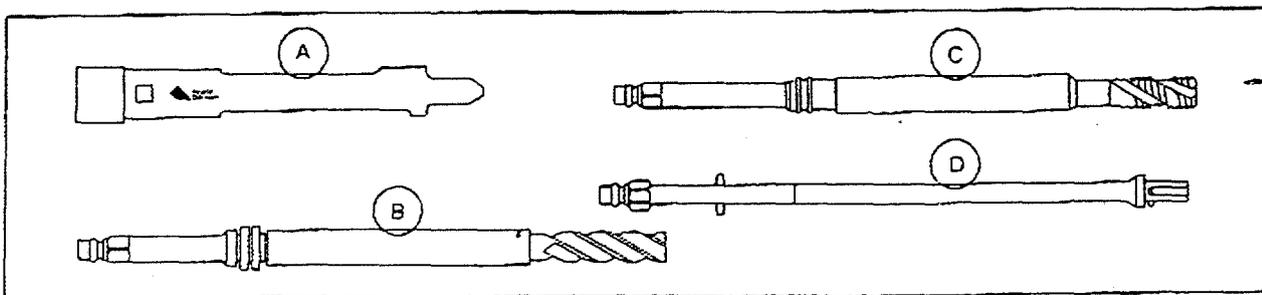
The Ray Threaded Fusion Cage™ device (RAY TFC™ device) is available in eight sizes, with 4 diameters (12 mm, 14 mm, 16 mm and 18 mm) and 2 lengths (21 mm or 26 mm). It is composed of Titanium 6A1-4V (extra low interstitial) alloy which conforms to the American Society for Testing and Materials (ASTM) F136-92. The Ray TFC™ device is used with anterior and posterior end caps which are available in corresponding diameters of 12 mm, 14 mm, 16 mm and 18 mm. The end caps are composed of ultra-high-molecular weight polyethylene (UHMWPE) which conforms to ASTM F648-84.



The Ray TFC™ device and end caps are implanted using a set of stainless steel instruments which conform to ASTM F899-94. The reusable stainless steel instrument set has two categories: size specific and universal. The size specific instruments correspond to the diameter of the Ray TFC™ device selected and are used for both cage lengths. The universal instruments are used regardless of cage size.

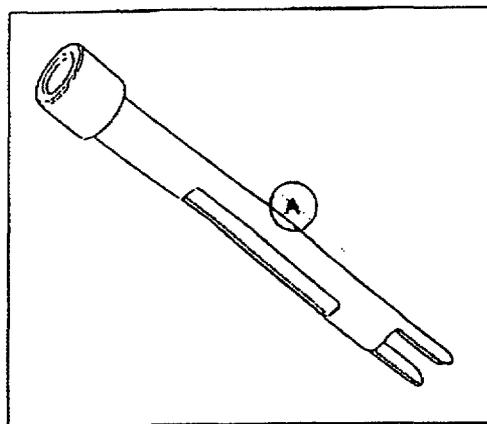
**SIZE SPECIFIC INSTRUMENT SET SCHEMATICS AND DESCRIPTIONS**

- A) Tang Retractor
- B) Vertebral Drill
- C) Vertebral Tap
- D) Cage Insertion Instrument



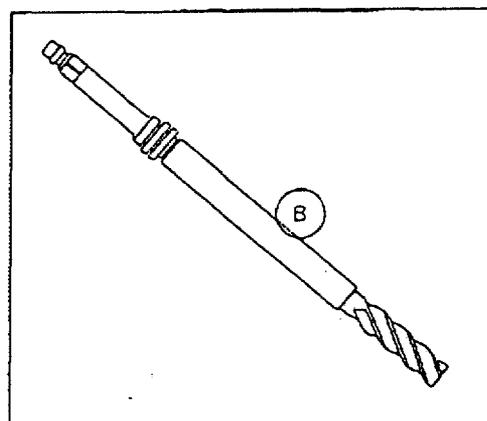
### A) TANG RETRACTOR

The Tang Retractor provides a central guide and alignment for all of the instruments used in the cage implantation and protects the delicate neural structures from coming into contact with the surgical instrumentation. The Tang Retractor is available in four sizes (12 mm, 14 mm, 16 mm, and 18 mm) to correspond to the cage size selected. The distal portion of the Tang Retractor has two flat, tapered projections that will seat within the intradiscal space. The total length of the instrument is 140 mm. The length of the tangs are 24 mm. The individual width of the tangs vary with the size of the Tang Retractor. Tang Retractor sizes of 12 mm, 14 mm, 16 mm and 18 mm have tang widths of 6 mm, 8 mm, 10 mm and 12 mm, respectively.



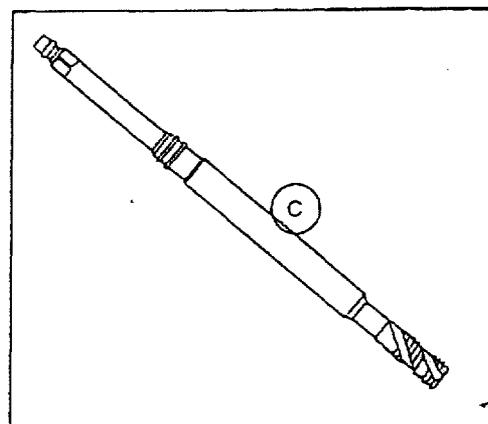
### B) VERTEBRAL DRILL

The Vertebral Drill is used for the removal of fibrous and nuclear material as well as to drill into the cortical endplate to initially prepare the bone bed. The Vertebral Drill is available in four sizes (12 mm, 14 mm, 16 mm, and 18 mm) to correspond to the cage size selected. The total length of the instrument is 241 mm. The portion of the instrument that is designed to fit within the cannula of the Tang Retractor is 176 mm. The distal end of the Vertebral Drill is a four fluted cutting surface intended to both end and side cut disc material and cortical bone.



### C) VERTEBRAL TAP

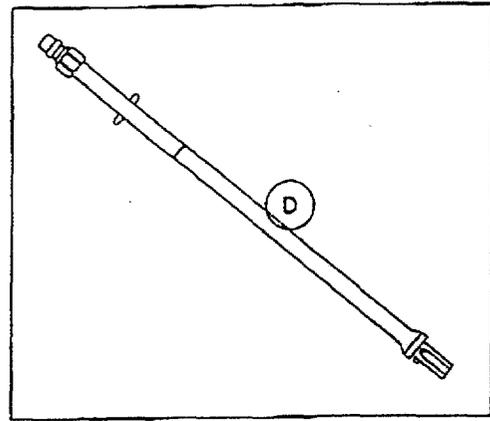
The Vertebral Tap is used to cut threads into the opposing vertebral endplates. The Vertebral Tap is available in four sizes (12 mm, 14 mm, 16 mm, and 18 mm) to correspond to the cage size selected. The total length of the instrument is 250 mm. The portion of the tap that is designed to fit within the cannula of the Tang Retractor is 170 mm. The tip of the Vertebral Tap is designed with a spiral, fluted thread pattern to cut into cortical bone.



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## D) CAGE INSERTION INSTRUMENT

The Cage Insertion Instrument places the Ray TFC™ device into the drilled and tapped hole. The Cage Insertion Instrument is available in four sizes (12 mm, 14 mm, 16 mm, and 18 mm) to correspond to the cage size selected. The total length of the instrument is 241 mm. The portion of the instrument that goes through the Tang Retractor to the depth marker line is 160 mm. The distal tip of the instrument is specially shaped to fit and hold the Ray TFC™ device. On the proximal portion of the shaft there is an indicator pin for cage orientation.



## UNIVERSAL INSTRUMENT SET SCHEMATICS

E) T-Handle

I) Chisel

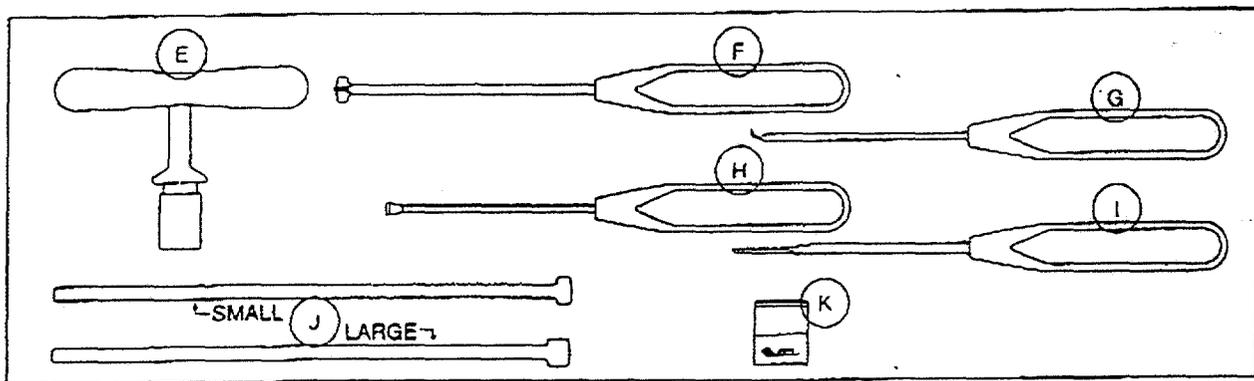
F) End Cap Insertion Instrument

J) Ganglion Retractors (small, large)

G) End Cap Removal Instrument

K) Impactor Cap (Tang Retractor Cap)

H) Bone Packing Instrument



## CAUTIONS

1. Prior to use, the instruments **MUST** be sterilized!
2. Inspect the instruments periodically for signs of wear or damage.
3. The instrument set for the Ray TFC™ device is specially designed and calibrated to work with this fusion cage only.
4. The components of this instrument set are not interchangeable with any other version of instruments.

## CLEANING

1. Remove all visible soil from the instrument and rinse in tap water immediately after use.
2. Place in an enzymatic detergent for no less than 90 minutes at 50° C.
3. Wash in an automatic dishwasher at 90° C.

## STERILIZATION

The Ray TFC™ Instrument set may be flash steam autoclaved or wrapped and sterilized in the usual manner. In general, the operators should follow the manufacturer's instructions for cycle parameters for sterilization. Either of the following cycles for sterilization times and temperatures are recommended:

### FLASH CYCLE

Temperature: 270° F-275° F (132° C-135° C) Time: 10 minutes

### COOL CYCLE

Temperature: 250° F-255° F (121° C-124° C) Time: 15 minutes

## WARNING

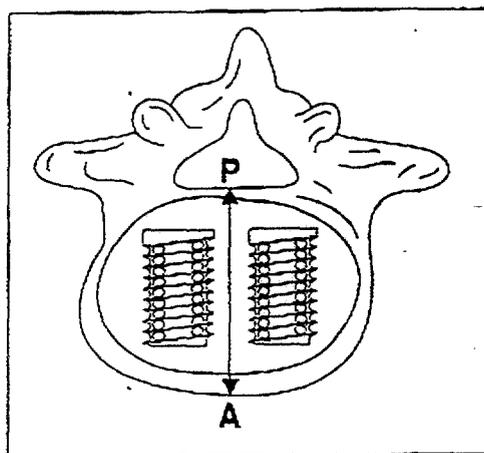
Implantation of a single cage per involved level is not recommended. The implantation of a single cage has been associated with cage fracture. Take this into consideration during preoperative planning and cage selection steps.

## PREOPERATIVE PLANNING AND CAGE SELECTION

1. The following radiographic studies are required for cage size determination:

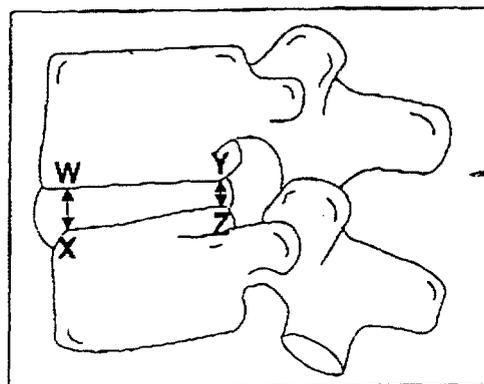
A/P and Lateral plain films, Ferguson view for L5-S1, Axial CT or MRI (CT templates may be ordered through Surgical Dynamics).

2. The CT or MRI studies will determine the cage length. Measure the vertebral body from P (posterior) to A (anterior). Allow for cage placement to be sufficiently lateral to accommodate the diameter of each cage, without touching each other in the midline. Allow for the natural curvature of the spine by providing a large enough surface area to better aid in load sharing. If the vertebral body measures > 32 mm in its mid-sagittal plane, the 26 mm cage is recommended. If the vertebral body measures < 32 mm in its mid-sagittal plane, the 21 mm cage is recommended.

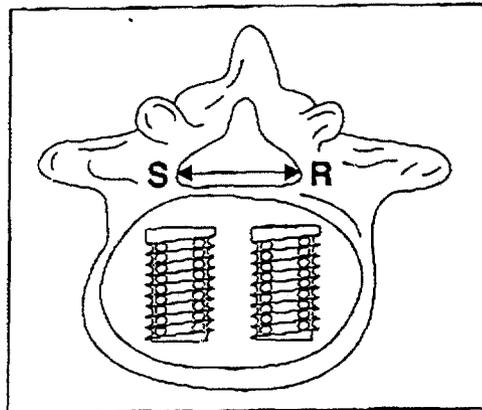


**NOTE: Implanted Ray TFC™ device should be approximately 3 mm from the anterior and posterior cortical margin of the endplates.**

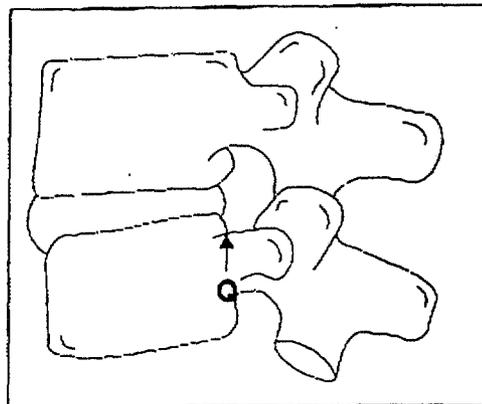
3. Lateral radiographs or sagittal MRI will determine the cage diameter. To determine the anterior disc height, measure from points W and X. Measure from points Y to Z to determine posterior disc height. When choosing the cage diameter, the size should allow for distraction to the patient's normal disc height and for tapping and penetration of the cage threads at least 3 mm into each vertebral endplate.



4. Attention needs to be paid to the interpedicular space. If the area between points **S** to **R** is too narrow, a substantial portion of the facet will need to be removed to accommodate the diameter of the cages. For example, two 16 mm cages will need an interpedicular space of 38 mm.



5. If the pedicle attachment to the inferior vertebral body is too close to the superior vertebral rim, when the Tang Retractor (**A**) is placed at point **Q**, it will tend to angle cephalad in the intradiscal space and will not allow for equal purchase of the vertebral endplates from the superior and inferior vertebral bodies. It may be necessary to remove the appropriate sections of bone to allow the intradiscal space to be drilled and tapped correctly, allowing for proper cage alignment within the intradiscal area.



#### OPERATIVE TECHNIQUE

PLIF procedures should be performed only by physicians having adequate training. In addition, medical literature and/or courses should be consulted relative to techniques, complications and hazards, prior to the performance of PLIF procedures.

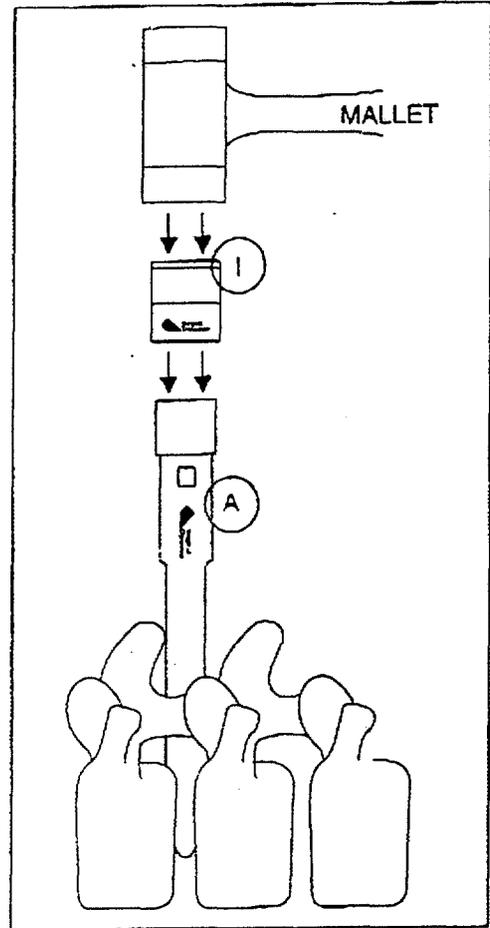
1. The patient is placed in the knee-chest position on a kneeling platform. Adjust the table so that the pelvis is parallel to the floor, and to accommodate for any discrepancies in femoral length.

2. After a standard PLIF approach has been performed and the correct vertebral level has been identified and confirmed, a circular laminotomy is performed on the first lateral side of the disc space using standard rongeurs, power drill or the Chisel (I). Care must be taken to protect all neural and vascular structures throughout the procedure.

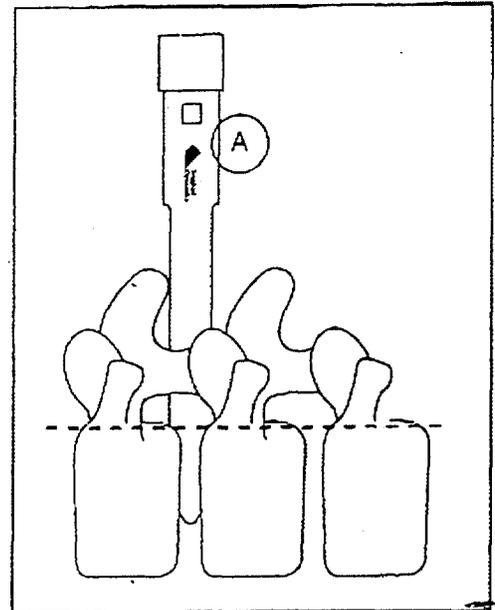
*Spill out*

*sf*

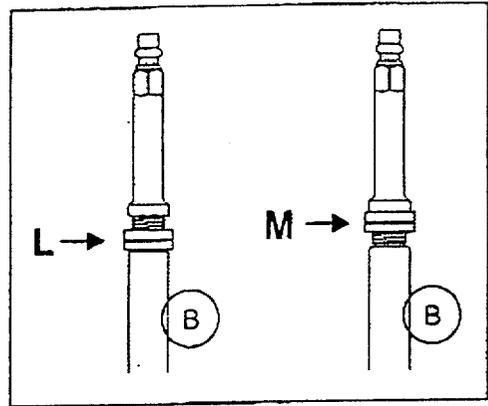
3. Using a small or large Ganglion Retractor (J), gently retract the ganglion to allow for placement of the Tang Retractor (A). Place the Impactor Cap (K) on the proximal end of the Tang Retractor and using a standard mallet, gently impact the retractor until it is seated firmly within the intradiscal space. Remove the Impactor Cap.



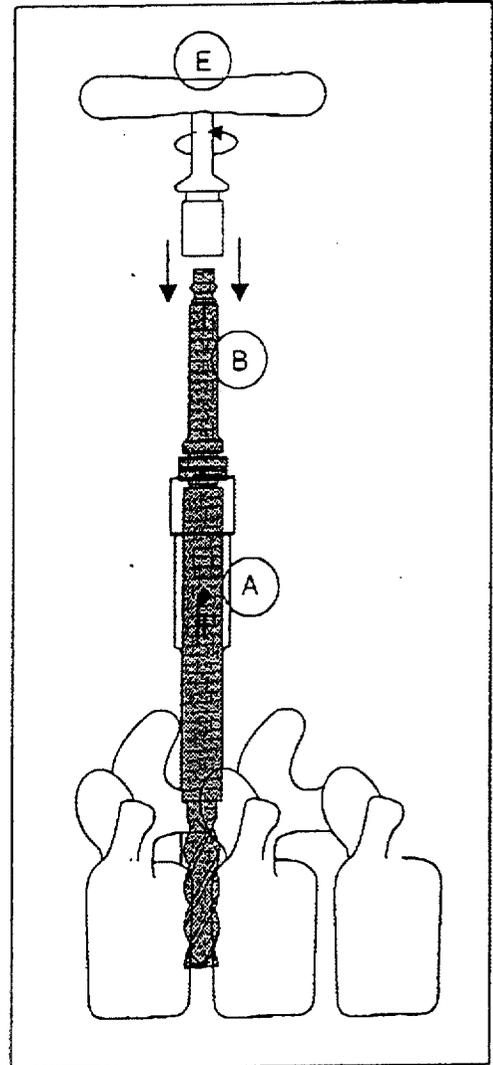
4. The Tang Retractor (A) is placed correctly when the tangs are fully inserted into the disc space and the distal end of the cannula portion is in contact with the superior and inferior vertebral bodies. Alignment of the retractor may be verified either visually or by a lateral x-ray.



5. Adjust the positive stops on the proximal end of the Vertebral Drill (B) shaft. For a 21 mm cage, fully advance both washers to the distal stop (L). For a 26 mm cage move both stops completely to the proximal position (M).



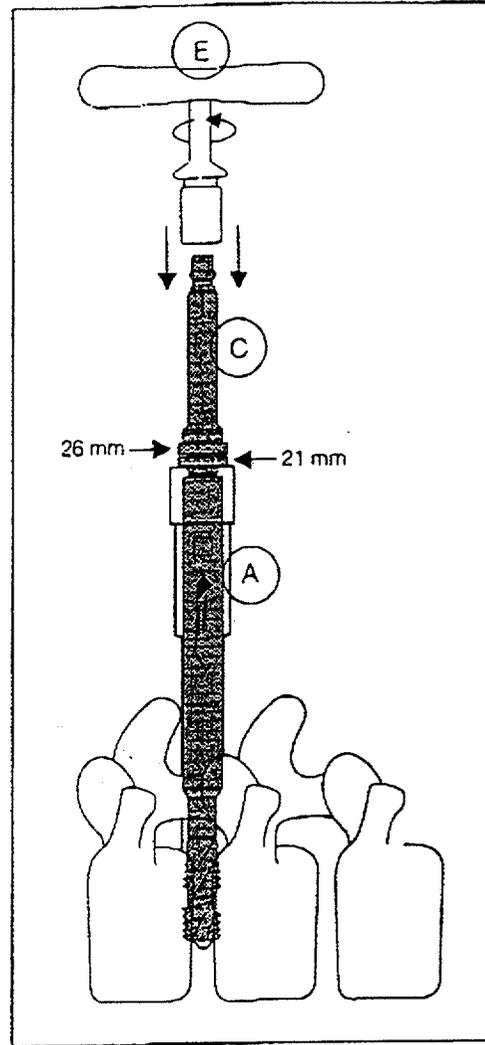
6. Place the T-Handle (E) onto the Vertebral Drill. **NOTE: Advance the Vertebral Drill through the Tang Retractor (A), turning the T-Handle clockwise until the positive stops engage the proximal end of the Tang Retractor. Remove drill assembly.**



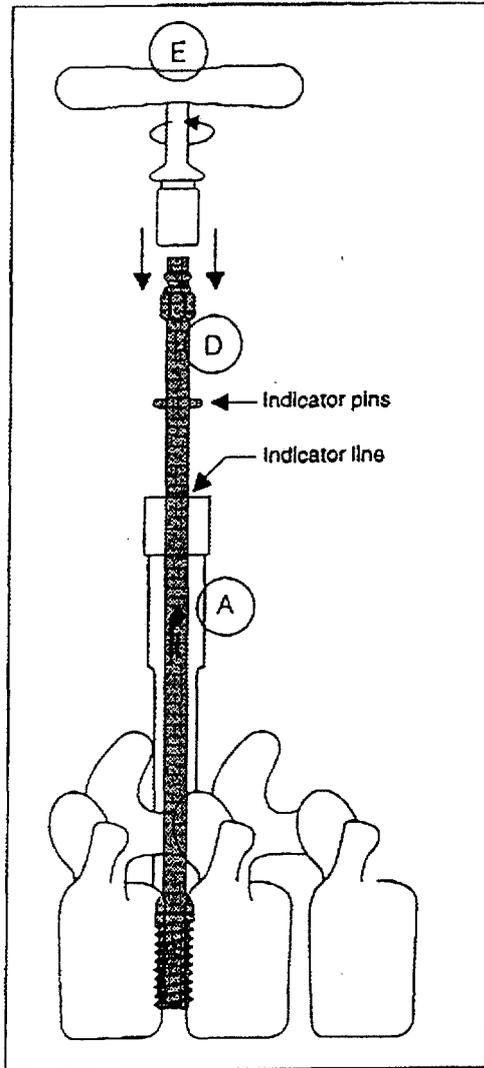
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7. Attach T-Handle (E) to the proximal end of Vertebral Tap (C) in the same fashion as the drill. Place tap assembly into Tang Retractor (A) and advance Vertebral Tap clockwise to desired depth. The Vertebral Tap has two raised ring markers to indicate depth. The distal ring is for use with a 21 mm cage and the proximal ring for a 26 mm cage. The Vertebral Tap should be advanced until the desired ring marker is level with the top of the Tang Retractor. Carefully unscrew the Vertebral Tap to remove the assembly.

**NOTE:** It is imperative that the Vertebral Tap be completely unscrewed counter-clockwise to prevent cross-threading of the space. Visually inspect the tapped hole to confirm proper threading.



8. Attach T-handle (E) onto the Cage Insertion Instrument (D) in the same fashion as the tap. Place the distal end of the Insertion Instrument into the posterior end of the Ray TFC™ device until it is fully engaged. Place the Insertion Instrument assembly into the Tang Retractor (A) and begin advancing the Ray TFC™ device into the prepared threaded hole by rotating clockwise. Advance the Ray TFC™ device until the laser etched indicator line on the Cage Insertion Instrument is level with the top of the Tang Retractor. Make sure that the indicator pins on the Insertion instrument shaft are pointed in a head-to-toe position. This will ensure that the cage is situated correctly, with the fenestrations contacting the tapped vertebral endplates and the solid lateral walls positioned within the disc space. To remove the Insertion Instrument, pull back gently and it will disengage from the cage.



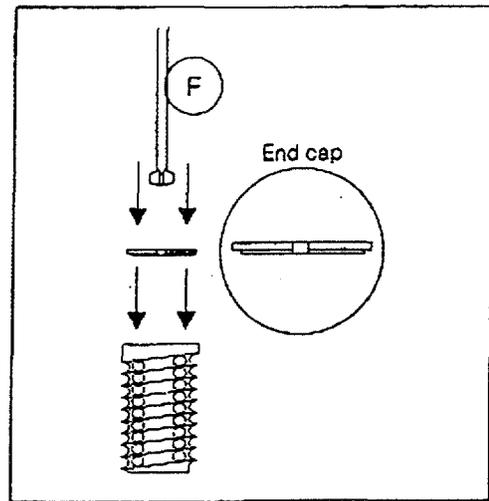
9. Repeat instructions 3-8 for the contralateral side.

10. Obtain autologous graft material following proper surgical technique. The approximate amount of graft material needed to fill each cage is:

- 6 cc's for **EACH PAIR** of 12 mm cages
- 8 cc's for **EACH PAIR** of 16 mm cages
- 12 cc's for **EACH PAIR** of 14 mm cages
- 16 cc's for **EACH PAIR** of 18 mm cages

Place graft material carefully inside each cage. Using the Bone Packing Instrument (H), pack the harvested bone into the cages, pressing the graft material into the internal arches of the cage wall. This will ensure that the graft material will be in close contact with the recipient bone of the vertebral endplates.

11. The cage is closed by placing the proximal end cap onto the End Cap Insertion Instrument (F) so that the flat surface of the end cap is facing the insertion instrument and the flanged surface is facing the cage. The rim of the end cap is snapped firmly into place within the internal groove of the posterior cage rim. If the end cap does not seat evenly or securely, use the End Cap Removal Instrument (G) to remove the end cap and repeat end cap insertion procedure.



12. The surgical site should be closed in the usual manner.

### **POSTOPERATIVE MANAGEMENT**

Establishment of a postoperative rehabilitation schedule that includes an exercise program for the patient is recommended. Additional recommendations include medication for pain control, bracing the patient for three months following surgery and physical therapy.

JB

## Patient Information Brochure

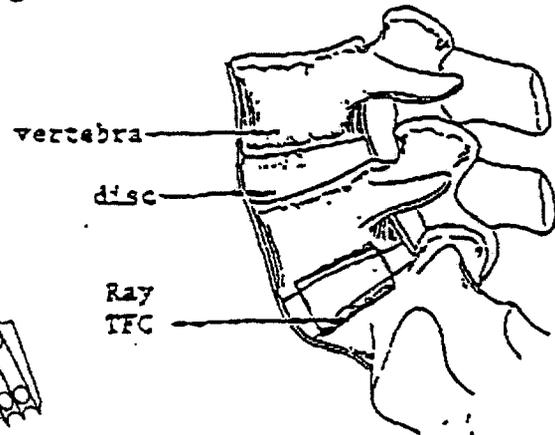
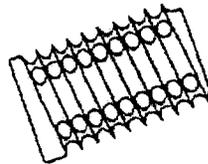
### **RAY THREADED FUSION CAGE (TFC)**

#### **INTRODUCTION**

This Patient Information Brochure was developed to help you make an informed decision about back surgery, specifically with the Ray Threaded Fusion Cage.

#### **WHAT IS THE RAY THREADED FUSION CAGE (Device Description)**

The Ray Threaded Fusion Cage is a hollow threaded cylinder with holes. The cage is made of titanium which is compatible with the human body. At each end of the cage is an end cap made from plastic, also compatible with the human body. The implants are filled with bone taken from your hip.



#### **WHICH PATIENTS MIGHT BENEFIT FROM THE RAY TFC**

In your back, there are five moveable vertebrae or bones that make up the lumbar or lower spine. Between each vertebrae is a cushion-like material called a disc. All bending, twisting, and turning movements occur through the discs. Your disc can wear down (degenerate) or dry out and cause some of your disc spaces to collapse. This may produce back and leg pain.

Based on your examination, your doctor is considering spinal surgery using the Ray TFC. This is because your doctor has found that you have low back pain due to a condition called degenerative disc disease (DDD). This results in pain coming from your disc. The purpose of this surgery is to stabilize and fuse one or two disc spaces of your spine and relieve your pain. Although your doctor is planning to use the Ray TFC for your condition, you should be aware that there are alternative treatments to this type of surgery. If you want information on these options, please discuss them with your doctor.

As a note, the Ray TFC is approved for use in patients with DDD. These patients with DDD may also have limited slippage of one vertebra over the vertebra below (Grade I spondylolisthesis). The Ray TFC, filled with bone taken from your hip, may be implanted from the 2nd lumbar disc (L2) down to the sacrum. Only one or two disc spaces are to be fused. Patients should be skeletally mature and have had at least six months of non-operative (conservative) treatment.

Above describes which patients might benefit from the Ray TFC. You should also be aware that the Ray TFC should not be used in patients with a severe infection at the operative site.

In addition, you should also be aware that there was little or no data for patients with the following conditions: previous fusion attempt of the same disc space(s), severe vertebral slippage of one vertebra over the vertebra below (spondylolisthesis-Grade II or above), DDD of three or more discs, conditions requiring steroids, serious illness, active drug abuse, gross obesity, severe loss of bone mass and density (osteoporosis) and pregnancy. Should you meet any of these conditions, please discuss this matter with your doctor.

## THE SURGERY

You will have surgery in an operating room. You will be given general anesthesia and will feel nothing during the actual procedure. Your doctor will make a standard surgical incision in your back (posterior approach) and after removing your worn disc, he will place two TFC cages in your disc space. These cages will then be packed with bone which your doctor will take from your hip. Your bone material is placed in the Ray TFCs so that bone may grow through the holes in the devices to fuse your disc space(s). He/she will place an end cap on each of the cages. After closing the incision, the procedure will be finished and you will go to the recovery room.

## AFTER SURGERY

For several days after the surgery you will probably be tired and have pain and discomfort. This is typical of any major operation and your doctor may control your pain with medication. The length of hospitalization will be determined by your doctor. You may be fitted with a spinal brace prior to being allowed to get out of bed. Bending and sitting need to be limited for a time after surgery. You may be prescribed a back brace for several months after surgery as determined by your doctor.

After you leave the hospital, your doctor may suggest physical therapy for several months. It is important for you to realize that you have undergone a surgical operation and that you should not participate in active competitive sports, heavy lifting, or strenuous exercises until you have been told by your doctor to do so. It is important to follow your doctor's instructions carefully in order to recover from your surgery as quickly as possible.

## POTENTIAL COMPLICATIONS

Complications related to spinal surgery include, but are not limited to, problems from anesthesia, circulatory problems, blood clots, heart attack, stroke, death, pneumonia, spinal fluid leaks, blood vessel damage/bleeding, infection, leg pain, bruises, bladder problems and nerve complications. The potential risks of this procedure are similar to those of other spinal surgeries. The rates of the specific complications reported in this study discussed below are provided in the Ray TFC package insert that was given to your doctor. If you have any questions about these complications, please talk to your doctor.

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## CLINICAL RESULTS

A 2-year clinical study of 236 patients with the Ray TFC was done at a number of hospitals. The success rates are shown below for overall success and for each major individual measure of success. The patients who were an overall success had successful results in all four of the major measurements (fusion, pain, function and muscle strength).

Success Parameters	Success Rates
<b>Overall Success (met all 4 below)</b>	<b>64%</b>
Fusion Rate	92%
Pain Improvement	76%
Function Maintenance or Improvement	96%
Muscle Strength Maintenance or Improvement	95%

Note that the number of patients used to calculate the success rates were slightly different for the measurements above due to some missing data. Please talk to your doctor if you have any questions regarding the above clinical information or about the statements in the following section.

From this 2-year clinical study, the following statements may be made about the Ray TFC:

- Younger patients had lower levels of pain and higher levels of function than older patients.
- Nonsmokers had lower levels of pain and higher levels of function than smokers.
- Patients with disc herniation had lower levels of pain than those without disc herniation.
- Older patients with L5-S1 involvement had higher levels of pain than older patients with other levels of involvement. In younger patients, there was no significant effect on pain based on level of involvement.
- Patients who had lower preoperative function scores showed lower levels of function through the study than those with higher preoperative scores.
- Older patients with L5-S1 involvement had lower levels of function than older patients with other levels of involvement. Additionally, older patients with lower preoperative function scores had lower levels of function than older patients with higher preoperative function scores. In younger patients, there was no significant effect on function based on level of involvement or preoperative function score.

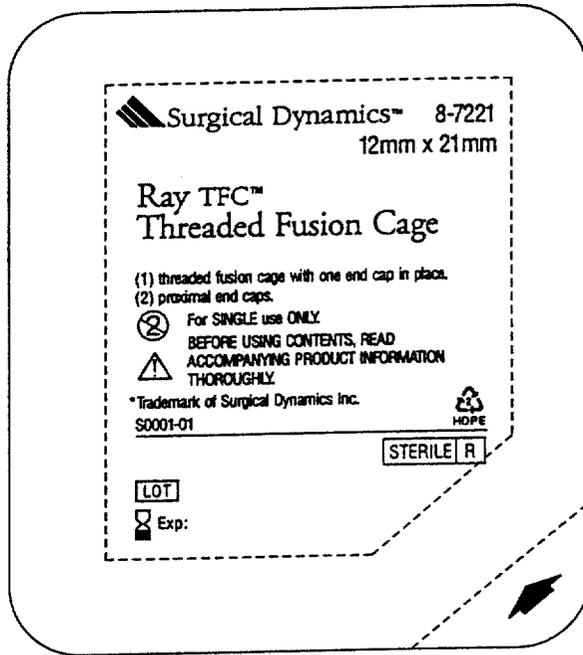
## QUESTIONS

If you have any questions or would like additional information, please ask your doctor.

rev. 10/8/96

Surgical Dynamics

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**Surgical Dynamics™** 8-7221  
**Ray TFC™** 12mm x 21mm  
**Threaded Fusion Cage**

Contents: Two (2) threaded fusion cages, each with one end cap in place.  
 Four (4) proximal end caps.

For SINGLE use ONLY. Unless opened or damaged, contents of package are STERILE.  
 DO NOT RESTERILIZE.

**BEFORE USING CONTENTS, READ ACCOMPANYING PRODUCT INFORMATION THOROUGHLY.**

**CAUTION:** U.S. federal law restricts this device to sale by or on the order of a physician with appropriate training or experience.  
 Made under one or more of U.S. Patents 4,961,740; 5,025,373 and foreign equivalents.

© 1996, Surgical Dynamics Inc. All Rights Reserved. Made in USA.

Contenu: Deux (2) cages de fusion.  
 Quatre (4) bouchons.

Vérifier l'intégrité du protecteur individuel de stérilité avant usage. NE PAS RESTERILISER.

**AVANT L'UTILISATION, LIRE ATTENTIVEMENT LE MODE D'EMPLOI ACCOMPAGNANT LE PRODUIT.**

Tous droits réservés. Fabriqué aux Etats-Unis.

Inhalt: Zwei (2) schraubbare Fusionsdübel, jeweils mit einer Verschlusskappe.  
 Vier (4) proximale Verschlusskappen.

Solange die Verpackung nicht geöffnet wurde oder beschädigt ist, ist der Inhalt jeder Packung STERIL. NICHT RESTERILISIEREN.

**VOR GEBRAUCH BEIGEFÜGTES HANDBUCH SORGFÄLTIG LESEN.**  
 Alle Rechte vorbehalten. Hergestellt in USA.

Contenuto: Due (2) threaded fusion cages, ogni uno dei quali con un cappuccio posto sull'estremità distale.  
 Quattro (4) cappucci per le estremità prossimali.

Se non aperto o danneggiato, il contenuto si intende STERILE. NON RISTERILIZZARE.  
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Contenido: Dos (2) jaulas de fusión enroscaables, cada una de ellas con un capuchón colocado en la parte distal.  
 Cuatro (4) capuchones para la extremidad proximal.

A menos que esté abierto o dañado, el contenido del envase es ESTERIL. NO REESTERILIZAR.

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12mm x 21mm  
8-7221

Ray TFC™  
Threaded Fusion Cage

Surgical Dynamics™

Surgical Dynamics™

Ray TFC™  
Threaded Fusion Cage

8-7221

12mm x 21mm

Contents:

Two (2) threaded fusion cages, each with one end cap in place.  
Four (4) proximal end caps.

For SINGLE use ONLY. Unless opened or damaged,  
contents of package are STERILE. DO NOT RESTERILIZE.

BEFORE USING CONTENTS, READ ACCOMPANYING  
PRODUCT INFORMATION THOROUGHLY.

CAUTION: U.S. federal law restricts this device to sale by or on  
the order of a physician with appropriate training or experience.

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Made from 100% Recycled Fibres  
Minimum 35% Post-Consumer Content

8-7221  
12mm x 21mm

2 Units/Unités/Stück/Unità/Unidades

Surgical Dynamics™

Ray TFC™  
Threaded Fusion Cage

Surgical Dynamics™

Ray TFC™  
Threaded Fusion Cage

8-7221

12mm x 21mm

<p>Contents:</p> <p>Deux (2) cages de fusion. Quatre (4) bouchons. Vérifier l'intégrité du protecteur individuel de stérilité avant usage. NE PAS RESTERILISER.</p> <p>AVANT L'UTILISATION, LIRE ATTENTIVEMENT LE MODE D'EMPLOI ACCOMPAGNANT LE PRODUIT.</p> <p>Tous droits réservés. Fabriqué aux Etats-Unis.</p>	<p>Inhalt:</p> <p>Zwei (2) schraubbare Fusionsdübel, jeweils mit einer Verschlusskappe. Vier (4) proximale Verschlussklappen. Solange die Verpackung nicht geöffnet wurde oder beschädigt ist, ist der Inhalt jeder Packung STERIL. NICHT RESTERILISIEREN!</p> <p>VOR GEBRAUCH BEGEFÜGTES HANDBUCH SORGFÄLTIG LESEN!</p> <p>Alle Rechte vorbehalten. Hergestellt in USA.</p>	<p>Contenido:</p> <p>Two (2) threaded fusion cages, one of the quali con un cappuccio posto sull'estremità distale. Cuatro (4) capucci per le estremità prossimali.</p> <p>Se non aperto e danneggiato, il contenuto di questo è STERILE. NON RESTERILIZZARE.</p> <p>PRIMA DELL'UTILIZZO LEGGERE ATTENTAMENTE LE AVVERTENZE SUL LIBRETTO INFORMATIVO.</p> <p>Tutti i diritti sono riservati. Prodotto negli USA.</p>	<p>Contenido:</p> <p>Dois (2) jéras de fusion evovocables, cada uno de ellas con un capuchón colocado en la parte distal. Cuatro (4) capuchones para la extremidad proximal.</p> <p>A menos que está abierto e dañado, el contenido del envase es ESTERIL. NO REESTERILIZAR.</p> <p>ANTES DE USAR EL CONTENIDO LEER ATENTAMENTE EL FOLLETO INFORMATIVO QUE LO ACOMPAÑA.</p> <p>Todos los derechos reservados. Fabricado en USA.</p>
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