



Smithsonian
National Museum of American History
Kenneth E. Behring Center

Guide to the Records of Think Surgical, Inc.

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by Alison Oswald

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Collection Overview

Repository:	Archives Center, National Museum of American History
Creator:	Think Surgical, Inc.. (Fremont, California)
Title:	Records of Think Surgical, Inc.
Dates:	1983-2010
Bulk Dates:	1991-1994
Quantity:	5.5 cubic feet, 17 boxes, 1 oversize folder
Abstract:	The collection documents the development of ROBODOC™, the first robot to perform surgery on a human in the United States through correspondence, memoranda, press clippings, press releases, engineering drawings, regulatory policies and procedures, photographs, and audiovisual materials.
Language:	Collection is in English.
Language:	Some materials in German.

Administrative Information

Acquisition Information

Collection donated by Think Surgical, Inc. through Dr. Mun In-Ki, CEO and President, April 2016.

Related Material

Materials in the Archives Center

Odex I Walking Robot Collection (AC0203)

Massie/McLurkin Innovative Lives Presentation and Interviews (AC0603)

Computer oral History Collection (AC0196)

Gerber Scientific Instrument Company Records (AC0929)

Processing Information

Collection processed by Alison Oswald, archivist, 2016.

Restrictions on Access

Collection is open for research.

Ownership & Literary Rights

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Historical

ROBODOC™ was the first robot to perform surgery in the United States. It was developed in 1986 by IBM's Thomas J. Watson Research Center, and researchers at the University of California, Davis. They formed a collaborative initiative to develop a surgical device for Total Hip Arthroplasty (THA). The team included William Bargar, M.D., Howard "Hap" Paul, D.V.M (1949- 1993), and engineers, Brent Mittelstadt and Peter Kazanides. See US Patent 5,769,092 for Computer-aided system for revision total hip replacement surgery and US Patent 5,806,518 for Method and system of positioning surgical robot, 1998. The original company, Integrated Surgical Systems (ISS) was incorporated in 1990.

The goal of ISS was to create a robotic surgical system that would redefine precision joint replacement procedures. Drilling into bone by hand is not always precise, and often requires glue to fill in empty spaces. Additionally there is a danger the bone will splinter. In this regard, ROBODOC is similar to computer-controlled machine tools. ROBODOC "mills" the bone or joint for accurate fitting similar to machine tools.

In May of 1990 the device was successfully tested on dogs. Since 1998 when it received 510 (K) clearance from the U.S. Food and Drug Administration for Total Hip Arthroplasty over 28,000 procedures have been performed worldwide.

ROBODOC™ was eventually sold in 2007 to Novatrix Biomedical, Inc. which formed Curexo Medical, Inc. to handle the acquisition of Integrated Surgical Systems, Inc. (ISS). ISS became THINK Surgical, Inc. in 2014.

Scope and Content Note

The collection documents the development of ROBODOC™, a robotic surgical system that would redefine precision joint replacement procedures. The collection contains correspondence, memoranda, press clippings, press releases, engineering drawings, regulatory policies and procedures, photographs, and audiovisual materials documenting the development of the ROBODOC™. The collection is strong in documentation about regulatory policies and procedures the company undertook for approval from the Food and Drug Administration.

Arrangement

The collection is divided into six series.

Series 1: Project History and Background Materials, 1985-2003

Series 2: Engineering Materials, 1989-2000, bulk 1991-1993

Series 3: User Guides, 1991-2001

Series 4: Food and Drug Administration, 1987-2001

Series 5: Press Clippings, 1983-2010

Series 6: Audiovisual Materials, 1988-2009

Names and Subject Terms

This collection is indexed in the online catalog of the Smithsonian Institution under the following terms:

Subjects:

Inventions--20th century
Inventions--21st century
Inventors--20th century
Inventors--21st century
Medical Equipment
Medical innovations
Orthopedics

Container Listing

Series 1: Project History and Background Materials, 1985-2003

This series consists of background materials and the history of the project primarily through correspondence.

Integrated Surgical Systems (ISS) , Inc., of Sacramento California was established in XXXX to develop computer-based, image-driven, surgical robotics systems. The company integrates sophisticated imaging and robotics technologies into precision application-oriented tools for exacting surgical procedures.

The company grew out of by Dr. Howard A. "Hap" Paul (1949-1993) and orthopaedic surgeon Dr. William Bargar (XXXX) collaboration with IBM's Thomas J. Watson Research Center and the University of California, Davis. In 1990, Robodoc™ Surgical Assistant System was successfully used by Dr. Paul to perform the world's first robotic-assisted total hip replacement surgery on a dog. ISS began a limited feasibility study of Robodoc™, authorized by the Food and Drug Administration for human surgery from 1992-1993 at Sutter General Hospital.

The Robodoc™ System consists of two integrated components which comprise the single turnkey system, the Orthodo™c preoperative planning workstation and Robodoc™, the computer controlled surgical robot.

Box 1, Folder 1	Biographical information (William Bargar, Brett Mittelstadt, Hap Paul, and Peter Kazanzides), 1993, 2011
Box 1, Folder 2	Dr. William Bargar (project time), undated
Box 1, Folder 3	Corporate identity, undated Includes Integrated Surgical Systems, Inc.; Robodoc, Curexo technology Corporation,; and Think Surgical, Inc.
Box 1, Folder 4	Integrated Surgical Systems, Inc. (company overview), undated
Box 1, Folder 5	Integrated Surgical Systems, Inc. (style guide), undated
Box 1, Folder 6	Interview notes of Hap Paul and William Bargar, 1986 May 7
Box 1, Folder 7	Correspondence, 1985-1993, 2003
Box 1, Folder 8	University of California, Davis (correspondence) Includes initial scope of work with IBM.
Box 1, Folder 9	University of California, Davis, 1985-1986
Box 1, Folder 10	University of California, Davis, 1988-1989
Box 1, Folder 11	Robodoc proposal, 1990
Box 1, Folder 12	Robodoc™, a robotic surgical system, undated
Box 1, Folder 13	Robodoc™, business plan, 1990 March 14
Box 1, Folder 14	Integrated Surgical Systems, Inc., business plan, 1993 September 29

- Box 1, Folder 15 ComputerWorld Smithsonian Awards Program, Integrated Surgical Systems, Inc., 1993 June 8

- Box 2, Folder 1 Non-homogenous material milling using a robotic manipulator with force controlled velocity, 1993
 Joel Zuhars, master thesis, University of California, Davis

- Box 2, Folder 2 Non-homogenous material milling using a robotic manipulator with force controlled velocity, [1993?]
 Joel Zuhars master thesis notes

- Box 2, Folder 3 Articles about Robodoc™, 1994-1998

- Box 2, Folder 4 Articles about hip replacement, 1992-1993

- Box 2, Folder 5 Bauer, Boerner, and Draenert. The Robodoc Assistance in Total Hip Replacement, 1998

- Box 2, Folder 7 Integrated Surgical Systems, Inc., Securities and Exchange Commission, Form S-3, registration statement, 1998 December 14

- Box 2, Folder 7 Integrated Surgical Systems, Inc., Securities and Exchange Commission, Form 10-Q and 10-QSB, 2001

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Series 2: Engineering, 1989-2000 (bulk 1991-1993)

This series consists of drawings, correspondence, memoranda, and notes detailing the development of the Robodoc™. The meeting summaries and design review documents provide insight into the review and decision making process for various aspects of development.

Box 3, Folder 2	Software development standard operating procedures, 1995
Box 3, Folder 3	System and method for performing image directed robotic orthopaedic procedures (US 6,033 415), 2000
Box 3, Folder 4	Pendant membrane switch panel, 1991-1992
Box 3, Folder 5	Pre-operative plan reading software test, 1992
Box 3, Folder 6	Design review and meeting summaries, 1991
Box 3, Folder 7	Problems with Robodoc™ system (review of November 7, 1991), 1991
Box 3, Folder 8	Design review and meeting summaries, 1992
Box 3, Folder 9	Design review and meeting summaries, 1993 January-1993 April
Box 3, Folder 10	Design review and meeting summaries, 1993 May-1993 June
Box 4, Folder 1	Design review and meeting summaries, 1993 August-1993 December
Box 4, Folder 2	Design review and meeting summaries, 1993 July
Box 4, Folder 3	Design review and meeting summaries, 1994 January
Box 4, Folder 4	Design review and meeting summaries, 1994 February-1994 November
Box 4, Folder 5	Design review memoranda, 1995
Box 4, Folder 6	Staff meeting summaries, 1997
Box 4, Folder 7	Engineering budget planning, 1998
Box 4, Folder 8	Bone motion detection documentation, 1991-1992
Box 5, Folder 1	Dacomobile (purchase order), 1991
Box 5, Folder 2	Electronics cabinet (purchase orders, notes, specifications and instructions), 1991
Box 5, Folder 3	Workstation assembly procedure, 1992
Box 5, Folder 4	Procurement specification, screw fastening kinematics plate to kinematic post, 1992 July 2
Box 5, Folder 5	Procurement specifications, pin style spanner wrench for fixator mounting, 1992 July 3
Box 5, Folder 6	Procurement specification, Robodoc thread mounting plate, 1992 July 3

Box 5, Folder 7	Procurement specification for swivel machine leveling mount for leg support, 1992 July 5
Box 5, Folder 8	Design document, isolation transformer, 1992
Box 5, Folder 9	Robodoc, rim box (purchase orders), 1991
Box 5, Folder 10	Anatomic medullary locking (AML) sizes and tolerance data, 1992
Box 5, Folder 11	Pin installation, kit sterilization procedure, 1992
Box 5, Folder 12	Labeling review, 1991-1992
Box 5, Folder 13	Specifications for labeling, 1992
Box 5, Folder 14	C.T. pin installation tools, 1992
Box 5, Folder 15	Robodoc operative report form, undated
Box 5, Folder 16	Specifications, pre-operative plan reading software, 1992
Box 5, Folder 17	Anteroposterior lateral fit data, 1997
Box 5, Folder 18	Transferring CT data to PC server (supplemental instructions for CT technicians), [1991?]
Map-folder 1	Robot Interface, RIM box (Drawing #100145), 1992 October 6 <i>8 drawings</i>
Map-folder 1	Robot Interface, RIM box (Drawing #100145), 1992 October 6 <i>6 drawings</i>
Map-folder 1	Operating room display stand (Drawing #100187), 1992 October 12 <i>7 drawings</i>
Map-folder 1	Kinematic diagnostic assembly, 1992 October 15 <i>1 drawing</i>
Box 17, Folder 1A	Pin location sleeve assembly and bearing sleeve, 1992 October 16 <i>10 drawings</i>
Map-folder 1	Orthodoc assembly, 1992 October 19 <i>6 drawings</i>
Map-folder 1	Robodoc surgical tool control cabinet, 1992 October 21 <i>6 drawings</i>
Box 17, Folder 1	Drawings, 101198 to 101295 (base for ROBODOC), 1994 <i>80 drawings</i>
Box 17, Folder 2	Drawings, 101301 to 101375 (base for ROBODOC), 1994 <i>10 drawings</i>
Box 17, Folder 3	Drawings, Eng 2000 to Eng 3000 (base for ROBODOC), 1994 <i>87 drawings</i>

Box 17, Folder 4	Drawings, Eng 20033 to Eng 20043 (base for ROBODOC), 1994 <i>5 drawings</i>
Box 17, Folder 5	Drawings, unidentified and drawing list, 1994 <i>18 drawings</i>
Map-folder 1	Wiring diagram, 1992 February 17
Box 3, Folder 1	Techmedica (implants), 1989-1990 <i>49 drawings</i>

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Series 3: User Guides, 1991-2001

Box 5, Folder 19	Orthodoc™ User Guide for the Orthopædic Surgeon, 1991
Box 6, Folder 1	Orthodoc™ User Guide, 1991-1993
Box 6, Folder 2	Orthodoc™ step-by-step templating, 1993
Box 6, Folder 3	Orthodoc™ User Manual (international edition), 1991-2000
Box 6, Folder 4	Orthodoc™ Bedienungsanleitung, 1991-1994
Box 6, Folder 5	Robodoc™ Preoperative Protocols, 1991-1993
Box 6, Folder 6	RFI compliance statement for German EMC/RFI law, 1993 April
Box 6, Folder 7	Robodoc™ Surgical Assistant System Postoperative CT Protocol for Robodoc Patients, 1993 April
Box 6, Folder 8	Robodoc™ Preoperative protocols (international edition), 1991-1999
Box 6, Folder 9	Robodoc™ Surgical Assistant System Pin Implantation and CT Protocols, 1991-1993
Box 7, Folder 1	Robodoc™ Surgical Assistant System and Orthodoc™ preoperative Planning System, 1997
Box 7, Folder 2	Robodoc™ User Guide, 1991-1993
Box 7, Folder 3	Robodoc™ User Manual (international edition, 1991-2001
Box 7, Folder 4	Robodoc™ User Manual (international edition) with illustrations, 1991-2001
Box 7, Folder 5	Robodoc™ Beidienungsanleitung (German translations), 1995
Box 7, Folder 6	JR3 Universal Force Moment Sensor System Operation Manual, 1993

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Series 4: Food and Drug Administration Materials, 1987-2001

This series consists of materials related to Food and Drug Administration (FDA) approval of Robodoc™ Surgical Assistant System. The materials include primarily correspondence, clinical trial data and agreements, notes, articles, study protocols, patient consent forms, clinical study case report forms and other materials created for institutional review committees. Many of the clinical trial documents provide condensed information about the device (Robodoc) protocols used, risk analysis, monitoring procedures, and consent forms. Also included is correspondence with Advanced Biosearch Associates (ABA), a contract Food and Drug Administration (FDA) regulatory and clinical research firm. ABA was founded in 1979 and is based in Danville, California.

Box 7, Folder 7	Regulations and publications, 1987-1988
Box 7, Folder 8	Advanced Biosearch Associates, 1991
Box 8, Folder 1	Robodoc™, brief history with FDA regulations, undated
Box 8, Folder 2	Institutional Review Board (notes and correspondence), 1990-1992
Box 8, Folder 3	Robodoc efficacy project, patient consent forms and protocols, 1991
Box 8, Folder 4	Investigational device exemption, comments and suggestions, 1991 January
Box 8, Folder 5	Code of Federal Regulations, Title 21, Part 812, Investigational Device Exemption, 1991 April
Box 8, Folder 6	General ORDB outline for clinical data presentations in premarket notifications and submissions, 1991 June
Box 8, Folder 7	Robotic instrumentation for cementless hip replacement, Department of health and Human Services (grant application), 1991-1992
Box 8, Folder 8	Robodoc™ protocols and consent, 1991 November
Box 8, Folder 9	Institutional Review Board (IRB) correspondence, 1991-1993 (bulk 1992)
Box 8, Folder 10	Robodoc™ Surgical Assistant System Investigational Plan, 1992 February 7
Box 9, Folder 1	Robodoc™ Surgical Assistant System Investigational Plan, Volume 1, 1992 May 27
Box 9, Folder 2	Robodoc™ Surgical Assistant System Investigational Device Exemption Applications, Volume 4, Exhibits 1-7, 1992 May 27
Box 9, Folder 3	Robodoc™ Surgical Assistant System Adjunct Clinical Study Protocol, 1992 September 22
Box 10, Folder 1	Robodoc™ Surgical Assistant System Investigational Exemption Application, Volume 4, Exhibits 1-5, 1992 September 8
Box 10, Folder 2	Robodoc™ multi-center trials, 1993
Box 10, Folder 3	Robodoc™ independent radiographic review, 1993 April

Box 10, Folder 4 Robodoc™ Surgical Assistant System multi-center trial (investigational exemption device application), 1993 May 6

Box 10, Folder 5 Robodoc™ Surgical Assistant System multi-center clinical trials, 1993 June 30

Box 10, Folder 6 Robodoc™ canine study protocol, 1993 July 7

Box 10, Folder 7 Robodoc™ Surgical Assistant System IDE number G920035, IDE Supplement, 1993 July 30

Box 11, Folder 1 Integrated Surgical Ssystems, Inc. (correspondence), 1993-1997

Box 11, Folder 2 Experimental subjects bill of rights and consent form, 1992

Box 11, Folder 3 Non-staff assist for Robodoc™ device training, 1993

Box 11, Folder 4 Robodoc™ Surgical Assistant System clinical study case form, 1993

Box 11, Folder 5 Notes for Food and Drug Administration rehearsal, 1996 October 5

Box 11, Folder 6 Robodoc™ Surgical Assistant System (background documents), 1997 December

Box 11, Folder 7 Robodoc™ histology (includes photographs of canine), 1997

Box 11, Folder 8 Robodoc™ meeting with Food and Drug Administration, 1998 February 19

Box 11, Folder 9 Robodoc™ Surgical Assistant PMA assignment and responsibilities for preparaion of PMA sections, 1998 March

Box 11, Folder 10 Robodoc™ Surgical Assistant U.S. multicenter study protocol, 1998-1999

Box 11, Folder 11 Conference call notes, 1998 October 11

Box 11, Folder 12 Advisory panel package, 1999 November 4

Box 12, Folder 1 Digimatch Robodoc™ Surgical System internal review committee, 2000

Box 12, Folder 2 Digimatch Robodoc™ Surgical System clinial trial, 2000-2001

Box 12, Folder 3 Digimatch Robodoc™ Surgical Assistance System (institutional review board materials), 2000-2001

Box 12, Folder 4 Patient questionnaires, 1989

Box 12, Folder 5 Robodoc™ Surgical Assistant System, adjunct clinical study protocol, 1992

Box 12, Folder 6 Robodoc™ clinical feasibility studies, 1993

Box 12, Folder 7 Robodoc™ Surgical Assistant , evaluation and results studies, 1997 December

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Box 12, Folder 9	Press clippings, 1986
Box 12, Folder 10	Press clippings, 1987-1989
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Box 13, Folder 1	Press clippings, 1992
Box 13, Folder 2	Press clippings, 1993
Box 13, Folder 3	Robodoc™ clinical trial announcement (press kit0, 1993 September 28 Image(s): Robodoc™ clinical trial announcement (press kit0 , 1993 September 28
Box 13, Folder 4	Press clippings, 1994-1995
Box 13, Folder 5	Press clippings, 1997
Box 13, Folder 6	Press clippings, 1998
Box 13, Folder 7	Press clippings, 2000-2001
Box 13, Folder 8	Press clippings, 2002
Box 13, Folder 9	Press clippings, 2003
Box 13, Folder 10	Press clippings, 2004
Box 13, Folder 11	Press clippings, 2005
Box 13, Folder 12	Press clippings, 2006
Box 13, Folder 13	Press clippings, 1007-2008
Box 13, Folder 14	Press clippings, 2010 Image(s)
Box 13, Folder 15	Press clippings, undated
Box 13, Folder 16	Techmedica product literature, 1986
Box 13, Folder 17	Photographs, undated Sutter General Hospital orthopaedic surgeons and staff

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Series 6: Audiovisual Materials, 1988-2009

- Box 14, Item AC1378-
OV0001 University of California, Davis, School of Medicine, television coverage of
ROBODOC, 1988 April 25
1 videocassette (vhs)
KGO-TV, Channel 7, 6:00 pm
- Box 14, Item AC1378-
OV0002 Sacramento News 10, 1987 February 17
1 videocassette (vhs)
Techmedia, Dr. Bargar and Dr. Paul at University of California Davis
- Box 14, Item AC1378-
OV0003 Robo-Dock, undated
1 videocassette (vhs)
Hap Paul, D.V.M., Assistant Clinical professor, Orthopaedics, University of
California, Davis
- Box 14, Item AC1378-
OV0004 Robodoc, IBM, 1989
1 videocassette (vhs)
Dr. William Bargar
- Box 14, Item AC1378-
OV0005 ROBODOC, 1989 April 1
1 videocassette (vhs)
KTXL Beyond Tomorrow
- Box 14, Item AC1378-
OV0006 First News 3, 1989 February 14
1 videocassette (vhs)
KVBC TV
- Box 14, Item AC1378-
OV0007 Robo-Doc, 1990 May 3-1990 May 10
1 videocassette (vhs)
Media coverage
- Box 14, Item AC1378-
OV0008 ROBODOC, 1990 July 1-1990 September 30
1 videocassette (vhs)
Media coverage
- Box 14, Item AC1378-
OV0009 ROBODOC at Sutter General Hospital, 1992 November 9
1 videocassette (vhs)
Press conference related
- Box 15, Item AC1378-
OV0010 First Robodoc cementless total hip replacement, 1992 November 7
1 videocassette (vhs)
Tom Lippert Productions, news release
- Box 15, Item AC1378-
OV0011 First ROBODOC cementless total hip replacement, 1992 November 7
1 videocassette (vhs)
Tom Lippert Productions, 30:00 minute version
- Box 15, Item AC1378-
OV0012 Sutter General Hospital, 1992
1 videocassette (vhs)
ROBODOC media coverage
- Box 15, Item AC1378-
OV0013 ROBODOC, undated
1 videocassette (vhs)
Media coverage on KPNX and WBRZ television

- Box 15, Item AC1378-
OV0014 Channel 10, undated
1 videocassette (vhs)
Dr. William Bargar
- Box 15, Item AC1378-
OV0015 ROBODOC, 2001 September 20
1 videocassette (vhs)
Total Running Time: 04:25
- Box 15, Item AC1378-
OV0016 Channel 10, 2002 April 19
1 videocassette (vhs)
Dr. William Bargar
- Box 15, Item AC1378-
OV0017 Roboto-Assisted Total Hip Arthroplasty, 2002
1 videocassette (vhs)
Total Running Time: 12 minutes
- Box 15, Item AC1378-
OV0018 Integrated Surgical Systems, ROBODOC #1, undated
1 videocassette (vhs)
- Box 15, Item AC1378-
OV0019 Integrated Surgical Systems, ROBODOC #1, undated
1 videocassette (vhs)
- Box 15, Item AC1378-
OV0020 Channel 13, ROBODOC, undated
1 videocassette (vhs)
KOVr television, includes Dr. William Bargar and Dr. Blumenfeld
- Box 16, Item AC1378-
OV0021 Dr. William Bargar talk
1 videocassette (vhs)
Total Running Time: 06:00 minutes
- Box 16, Item AC1378-
OV0022 Integrated Surgical Systems, ROBODOC, undated
1 videocassette (vhs)
- Box 16, Item AC1378-
OV0023 Immi, undated
1 videocassette (vhs)
Engineering copy
- Box 16, Item AC1378-
OV0024-25 Integrated Surgical Systems, ROBODOC II
1 videocassette (vhs)
Engineering demo copy
- Box 16, Item AC1378-
DVD0026 ROBODOC 3.4, 2008 March 4
1 electronic disc (dvd)
- Box 16, Item AC1378-
OV0027 Dr. William Bargar video with Food and Drug Administration, undated
1 electronic disc (dvd)
- Box 16, Item AC1378-
DVD0028 Dr. William Bargar, undated
1 electronic disc (dvd)
B-roll, scenes 1 and 2
- Box 16, Item AC1378-
DVD0029 ORTHODOC 5.0, 2009 November 20
1 electronic disc (dvd)
Training video

- Box 16, Item AC1378-
CD0030 ROBODOC brochure materials, undated
 1 *electronic disc (cd)*
 Power point
- Box 16, Item AC1378-
DVD0031 Four surgeries, undated
 1 *electronic disc (dvd)*
- Box 16, Item AC1378-
DVD0032 ROBODOC Presentation, undated
 1 *electronic disc (dvd)*
- Box 16, Item AC1378-
DVD0033 ROBODOC, undated
 1 *electronic disc (dvd)*
 THA post and TKA
- Box 16, Item AC1378-
CD0034 ROBODOC cement removal, 2008 April
 1 *electronic disc (cd)*
- Box 16, Item AC1378-
DVD0035 ROBODOC, undated
 1 *electronic disc (dvd)*
 Hip revision and primary knee procedures
- Box 16, Item AC1378-
DVD0036 Discovery Channel, Smart Tools Excerpt, 2004 February
 1 *electronic disc (cd)*
 ORTHODOC and ROBODOC presentations
- Box 16, Item AC1378-
DVD0037 ROBODOC, Discovery Channel Smart Tools Excerpt, undated
 1 *electronic disc (cd)*
- Box 16, Item AC1378-
DVD0038 ROBODOC segment on Discovery Channel, undated
 1 *electronic disc (cd)*
- Box 16, Item AC1378-
DVD0039 ROBODOC, knee procedure with animation, [2008?]
 1 *electronic disc (cd)*

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