U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K063166 - 217 pages
COMPANY:	I.T.S. IMPLANTAT-TECHNOLOGIE-SYSTEME GMBH (ITSIMPL)
PRODUCT:	PLATE, FIXATION, BONE (HRS)
SUMMARY:	Product: I.T.S. PELVIC RECONSTRUCTION SYSTEM
DATE REQUESTED:	Apr 27, 2016
DATE PRINTED:	Apr 27, 2016
Note:	Printed

K063166

Section XII: 510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990

510(k) Summary

DEC 2 2 2006

NAME OF FIRM: I.T.S. Implantat-Technologie-Systeme GmbH.
Autal 28.
Lassnitzhoehe A – 8301
AUSTRIA

510(k) FIRM CONTACT: Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372

TRADE NAME: Pelvic Reconstruction System (PRS)

COMMON NAME: Pelvic Bone Fixation Set

CLASSIFICATION: Plate, Fixation, Bone (see 21 CRF, Sec. 888.3030),
Pin, Fixation, Threaded (see 21 CRF, Sec. 888.3040)
Screw, Fixation, Bone (see 21 CFR, Sec. 888.3040),
Washer, Bolt, Nut (see 21 CFR, Sec. 888.3030)

DEVICE PRODUCT CODE: HRS

SUBSEQUENT PRODUCT CODE: JDW, HWC, HTN

SUBSTANTIALLY EQUIVALENT DEVICES
Synthes 3.5mm Low Profile Pelvic Reconstruction **(K031573)**
Stryker Trauma Pelvic Set **(K001614)**
Zimmer Pelvic Reconstruction Set
Synthes Sacral Bar System **(K001720)**
I.T.S. GmbH FR.O.H. Calcaneus Repair System **(K051642)**
Synthes 3.9mm Pelvic Screw **(K013044)**
I.T.S. Straight Plate with Angular Stability & Screw System **(K060156)**

DEVICE DESCRIPTION: The I.T.S. Pelvic Reconstruction System (PRS) encompasses a number of fracture fixation subsystems (multiple pelvic plate designs, sacral threaded rod, and cannulated screw & washer) for facture fixation and reconstruction of pelvic ring fractures in the pelvis.

The I.T.S. PRS Low Profile – Multiple Type – Pelvic Plating System consists of the following plate types: 1) A Straight Plate at a 2.5mm thickness with 10 to 14 hole length sizes, 2) A Curved Plate with a 108mm radius at a 2.5mm thickness with 4 to 16 hole length sizes, 3) A Curved Plate with a 88mm radius at a 2.5mm thickness also with 4 to 16 hole length sizes, 4) A Symphysis Plate at a 4.0mm thickness in both a 4 & 6 hole size, 5) A SacroIlliac-Joint (SIJ) L-Shaped Plate at a 2.5mm thickness in a left and right 5 hole size, and 6) A SIJ Closed Plate at a 2.5mm thickness in a 4 hole size.

All plate designs are low profile in thickness and made from CP Titanium. The PRS Pelvic Plating System also encompasses a number

of Cancellous (5.9mm std.compression & 5.9mm Locking screws) and Cortical (4.5mm std.compression screw) screw types and length sizes. All bone screws are pre-drilling and self-tapping in design and manufactured from high strength 6-4 Alloyed Titanium. All components (plates & screws) have a TIODIZE II surface treatment preparation.

The I.T.S. PRS *Sacral Rod System* consists of a threaded pin, wedge-shaped washers, and nut/locknut design with one end of the threaded pin having a trocar point. The assembled unit is used to stabilize ilio-iliac posterior pelvic ring disruption injuries. All components are manufactured from high strength 6-4 Alloyed Titanium material and have the TIODIZE II surface preparation.

The I.T.S. PRS *7.3mm Cannulated SIJ Traction Screw & Washer* is a pre-drilling, self-tapping, and back-tapping screw design for guided reduction of pelvic bone fractures. Washers (flat & curved) are available for use with the screw. All 7.3mm Cannulated Screws & washers are manufactured from high strength 6-4 Alloyed Titanium and have the TIODIZE II surface preparation.

INTENDED USE:

The ***intended use*** of the I.T.S. Pelvic Reconstruction System (PRS) is to stabilize one or more pelvic bone fractures in the pelvic ring area of the pelvis of an adult or pediatric patient which include the use of the following pelvic fracture fixation systems.

Indications for use of the I.T.S. PRS Low Profile - Multiple Type – Pelvic Plating System include:
1) Fracture reconstruction of the acetabulum, sacrum, illium, and entire pelvic ring,
2) Revision surgery of pseoduarthroses, non-unions and mal-unions,
3) Ilio-Iliac distance osteosynthesis,
4) Osteotomies,
5) Arthrodesis,
6) Sacroiliac joint dislocations, and
7) Symphysis pubis disruptures

Indications for use of the I.T.S. PRS Sacral Rod System include:
1) Fixation of fractures of the posterior pelvis,
2) Fixation of fractures of the posterior iliac spine,
3) Fixation of fractures of the posterior inferior iliac spine,
4) Dorsal stabilization of the posterior pelvic ring for unstable pelvic ring injuries,
5) Fixation of sacral fractures, and
6) Fracture dislocations of the sacro-iliac joint

Indications for use of the I.T.S. PRS 7.3mm Cannulated SIJ Traction Screw & Washer include fracture fixation of pelvic bone fractures where indicated and for periacetabular osteotomies.

The system(s) has not been studied in spinal use, and is not intended for use in vertebral column fracture or fusion procedures.

BASIS OF SUBSTANTIAL EQIVLAENCE:

The I.T.S. Pelvic Reconstruction System (PRS) is substantially equivalent to the Synthes, Zimmer, and Stryker pelvic reconstruction systems and the I.T.S. GmbH stabilizing bone plating systems.

SUMMARY OF SAFETY AND EFFECTIVENESS:

The I.T.S. Pelvic Reconstruction System (PRS) is shown to be safe and effective for use in 'pelvic ring' bone fracture fixation of the pelvis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

I.T.S Implantat-Technologie-Systeme GmbH
% Mr. Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th Street
Prior Lake, Minnesota 55372

DEC 2 2 2006

Re: K063166
Trade/Device Name: Pelvic Reconstruction System (PRS)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, JDW, HWC
Dated: October 13, 2006
Received: October 18, 2006

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Bruch MD

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) NUMBER: K063166

DEVICE NAME: **PELVIC RECONSTRUCTION SYSTEM (PRS)**

The ***intended use*** of the I.T.S. Pelvic Reconstruction System (PRS) is to stabilize one or more pelvic bone fractures in the 'pelvic ring' area of the pelvis of an adult or pediatric patient which include the use of the following pelvic fracture fixation systems.

Indications for use of the I.T.S. PRS Low Profile - Multiple Type – Pelvic Plating System include:
1) Fracture reconstruction of the acetabulum, sacrum, illium, and entire pelvic ring,
2) Revision surgery of pseoduarthroses, non-unions and mal-unions,
3) Ilio-Iliac distance osteosynthesis,
4) Osteotomies,
5) Arthrodesis,
6) Sacroiliac joint dislocations, and
7) Symphysis pubis disruptures

Indications for use of the I.T.S. PRS Sacral Rod System include:
1) Fixation of fractures of the posterior pelvis,
2) Fixation of fractures of the posterior iliac spine,
3) Fixation of fractures of the posterior inferior iliac spine,
4) Dorsal stabilization of the posterior pelvic ring for unstable pelvic ring injuries,
5) Fixation of sacral fractures, and
6) Fracture dislocations of the sacro-iliac joint

Indications for use of the I.T.S. PRS 7.3mm Cannulated SIJ Traction Screw & Washer include fracture fixation of pelvic bone fractures where indicated and for periacetabular osteotomies.

The system(s) has not been studied in spinal use, and is not intended for use in vertebral column fracture or fusion procedures.

Prescription Use X AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Barbara Buchinski

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063166

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

I.T.S Implantat-Technologie-Systeme GmbH
% Mr. Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th Street
Prior Lake, Minnesota 55372

DEC 2 2 2006

Re: K063166
Trade/Device Name: Pelvic Reconstruction System (PRS)
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1

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Sincerely yours,

Barbara Bucher MD

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Aufal 28, 8301 Lassnitzhöhe / G
AUST

Indications for Use

510(k) NUMBER: K063166

DEVICE NAME: **PELVIC RECONSTRUCTION SYSTEM (PRS)**

The ***intended use*** of the I.T.S. Pelvic Reconstruction System (PRS) is to stabilize one or more pelvic bone fractures in the 'pelvic ring' area of the pelvis of an adult or pediatric patient which include the use of the following pelvic fracture fixation systems.

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Prescription Use X AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Barbara Buchinsky

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number K063166

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

October 18, 2006

I.T.S. IMPLANTAT-TECHNOLOGIE-SYSTEM
C/O ENGINEERING CONSULTING SERVICES
3150 E. 200TH ST.
PRIOR LAKE, MN 55372
ATTN: AL LIPPINCOTT

510(k) Number: K063166
Received: 18-OCT-2006
Product: I.T.S. PELVIC RECONSTRUCTION SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k))Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k). 3)Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRHs e-Copy Program, you may replace one paper copy of an premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have policy or procedural questions, please contact anyone on the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

K063166

Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN. 55372

(952) 492-5858 TEL
(952) 492-5859 FAX

October 13, 2006

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center, HFZ-401
1390 Piccard Drive
Rockville, MD 20850

K-24

Re: 510(k) Notification – I.T.S. GmbH Pelvic Reconstruction System (PRS)

Dear Sir/Madam,

Enclosed is a submission pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act and the regulations contained in Title 21 CFR 807. This submission is to notify the FDA of our intent to market the I.T.S. Pelvic Reconstruction System (PRS). We believe this fracture fixation system to be substantially equivalent to other pelvic bone fixation devices that are commercially available in the U.S..

Attached is the FDA Form # 3601 and copy of Check # [redacted] **showing the 'User Fee' payment with PIN** [redacted] **via overnight Registered Priority Mail on 10-10-2006.**

Some of the information contained herein is considered **PROPRIETARY** and is stamped accordingly.

*Included in this submission in Section I is a **Truthful and Accurate Statement**, in Section XI is an **Indications Enclosure**, and in Section XII is a **510(K) Summary**.*

Please direct any inquiries concerning this submission to **Al Lippincott**, Engineering Consulting Services, Inc., *U.S. Agent and Official Correspondent to I.T.S. Implantat-Technologie-Systeme GmbH.*, at **(952) 492-5858** or FAX **(952) 492-5859**.

Thank you for your prompt attention to this submission.

Sincerely,

Al Lippincott
U.S. Agent and Official Correspondent for I.T.S. Implantat-Technologie-Systeme GmbH

Enclosure: **510(k) Submission - I.T.S. GmbH - Pelvic Reconstruction System (PRS)**

K26
OR
II

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Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: b(4) [redacted]
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

-->

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

ITS IMPLANT TECHNICAL SYSTEMS GMBH (ASUTRIA)
3150 e. 200th. St.
Prior Lake MN 55372
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
411825819

2. CONTACT NAME
Albert Lippincott III

2.1 E-MAIL ADDRESS
allippincott@msn.com

2.2 TELEPHONE NUMBER (include Area code)
952-492-5858

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
952-492-5859

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
b(4) [redacted]
09-Oct-2006

Form FDA 3601 (08/2003)

Close Window

17

ENGINEERING CONSULTING SERVICES, INC.
3150 E. 200TH STREET
PRIOR LAKE, MN 55372
(952) 492-5858

(b)(4) [redacted]

b(4) [redacted]

10/9/2006

PAY TO THE ORDER OF Food and Drug Administration

$ b(4) [redacted]

b(4) [redacted]

ENGINEERING CONSULTING SERVICES, INC.
Food and Drug Administration
10/9/2006
Consulting:FDA 'User Fee' 510(k) Application Fee for PRS for I.T.S. Austria

b(4) [redacted]

b(4) [redacted]

Business Checking - b(4) [redacted]

b(4) [redacted]

ENGINEERING CONSULTING SERVICES, INC.
Food and Drug Administration
10/9/2006
Consulting:FDA 'User Fee' 510(k) Application Fee for PRS for I.T.S. Austria

b(4) [redacted]

b(4) [redacted]

Business Checking - b(4) [redacted]

b(4) [redacted]

510(k) Submission
I.T.S. Implantat-Technologie-Systeme GmbH
Pelvic Reconstruction System (PRS)

Table of Contents:

I.T.S. Implantat-Technology-Systems GmbH
Geschäftsführende Gesellschafterin: Dr. Eva Ruprechter
Autal 28, 8301 Lassnitzhöhe / Graz
AUSTRIA
Tel ++43 (0)316 211 21
Fax ++43 (0)316 211 21 2
office@its-implant.com

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

(As required By 21 CFR 807.87(j))

I certify, in my capacity as president of I.T.S. Implantat-Technologie-Systeme GmbH, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Signed

.....
Dr. Eva Ruprechter

06/10/2006 Oct. 6, 2006
.....
Dated

.....
Premarket Notification (510(k)) Number

FN 163966 b
ARA LN 5062
DVR 0934704
ATU 43757109
EN ISO 13485
EN ISO 9001

Section II: Manufacturer Identification

1. **Name and Address of Manufacturer:**

I.T.S. Implantat-Technologie-Systeme GmbH
Autal 28
Lassnitzhoehe A – 8301

AUSTRIA

2. **Sponsor of the 510(k) submission:**

I.T.S. Implantat-Technologie-Systeme GmbH
Autal 28
Lassnitzhoehe A – 8301

AUSTRIA

3. **Manufacturer's Registration Number:**

Registration No.: **3004369035**

Owner/Operator No.: **9059922**

4. **Contact Person for All Correspondence:**

Al Lippincott,

U.S. Agent and Official Correspondent for I.T.S. Implantat-Technologie-Systeme GmbH

Engineering Consulting Services, Inc.
3150 E. 200th. St.
Prior Lake, MN. 55372

Telephone Number:	**(952) 492-5858**
FAX Number:	**(952) 492-5859**
Cell Number:	(b) (6) [redacted]
E-mail:	**allippincott@msn.com**

Section III: Device Identification

1. **Proprietary Name:** I.T.S. Pelvic Reconstruction System (PRS)

2. **Common Name**: Pelvic Bone Fixation Set

3. **Classification Name and Reference:**

Plate, Fixation, Bone	*(see 21 CRF, Sec. 888.3030)*
Pin, Fixation, Threaded	*(see 21 CFR, Sec. 888.3040)*
Screw, Fixation, Bone	*(see 21CFR, Sec. 888.3040)*
Washer, Bolt Nut	*(see 21CFR, Sec. 888.3030)*

4. **Device Classification for the subject device and/or predicate device:**

   Class II

5. **Proposed Regulatory Class:** Class II

6. **Device Product Code:** HRS

7. **Subsequent Product Codes:** JDW, HWC, HTN

8. **Panel Code:** Orthopedics/Part 87

Section IV: Device Background

The **I.T.S. Pelvic Reconstruction System (PRS)** is a low profile - multiple design - pelvic plating, sacral rod securing and guided cannulated screw - *group of fracture fixation systems* - for fracture fixation of disruptive bone fracture injuries to the pelvic region in an adult or pediatric patient.

The I.T.S. PRS Low Profile – Multiple Type – Pelvic Plating System comes with a full complement of pelvic plate types in multiple hole and length sizes as: (1) Straight, (2) 108mm - radius Curved, (3) 88mm - radius Curved, (4) Symphysis, (5) SIJ L-shaped Left & Right, and (6) SIJ Closed. All plate types have a smooth and rounded profile and are contourable in three planes. All low profile plates accept a screw-to-plate head locking feature as a 5.9mm cancellous screw to create a stable, fixed angle, construct between the plate and screw(s). A standard 4.5mm cortical and 5.9mm cancellous compression screw is also available to facilitate reduction and create compression between the plate and bone. All screws are pre-drilling and self-tapping in design. The plate design is made from CP Titanium, a known biocompatible material, with a TIODIZE II surface treatment – which improves the material surface hardness and biocompatibility to adjacent tissues. The high strength 6-4 Alloyed Titanium cancellous and cortical screws allow a ±20° angle for positioning in relation to the plate so as to secure maximum purchase with bone. The low-profile plate design minimizes soft-tissue irritation in the pelvic region for the patient. A full compliment of instrumentation is available for use with the system.

510(k) Submission
I.T.S. Implantat-Technologie-Systeme GmbH
Pelvic Reconstruction System (PRS)

The I.T.S. PRS 7.3mm Cannulated SIJ Traction Screw & Washer is a complement of various length cannulated screws in a 7.3mm size with a variable thread length for guided fixation of pelvic bone fractures. All screws feature a cancellous thread form and are pre-drilling, self-tapping, and back-tapping (if removal is necessary) in design. All screws are used in conjunction with a 3.2mm guide wire and x-ray imaging for precise placement in bone across a pelvic bone fracture site. Washers (flat and curved) are available for thin cortex or osteopenic bone where the screw head may break through. The cannulated screw and washers are made from high strength 6-4 Alloyed Titanium material and have a TIODIZE II surface treatment for increased surface material hardness and biocompatibility to adjacent tissue. A full compliment of instrumentation is available for use with the system.

The I.T.S. PRS Sacral Rod System consists of a 'each-end threaded' pin, wedge-shaped washers, and nut/locknuts construct. One end of the threaded pin has a trocar point to assist in guiding the pin through pre-drilled holes if the guiding instrument is not used. The unit is assembled with one(1) 'each-end threaded' pin, two(2) wedge-shaped washers and two(2) nut/locknuts for stabilizing ilio-iliac posterior 'pelvic ring' disruption injuries. Typically, two assembled units are used for stabilizing the 'pelvic ring' injury. The threaded pin, wedge-shaped washers, and nut/locknut are manufactured from high strength 6-4 Alloyed Titanium material and are surface treated with the TIODIZE II surface treatment for increased material surface hardness and biocompatability to adjacent tissues. Again, a full complement of instrumentation is available for use with the system.

510(k) Submission
I.T.S. Implantat-Technologie-Systeme GmbH
Pelvic Reconstruction System (PRS)

The attached brochure documents from I.T.S. GmbH describe the surgical technique and give examples of use for the multiple type - pelvic plating, sacral rod, and cannulated screw Pelvic Reconstruction System (PRS) along with a device listing of all implants and instrumentation.

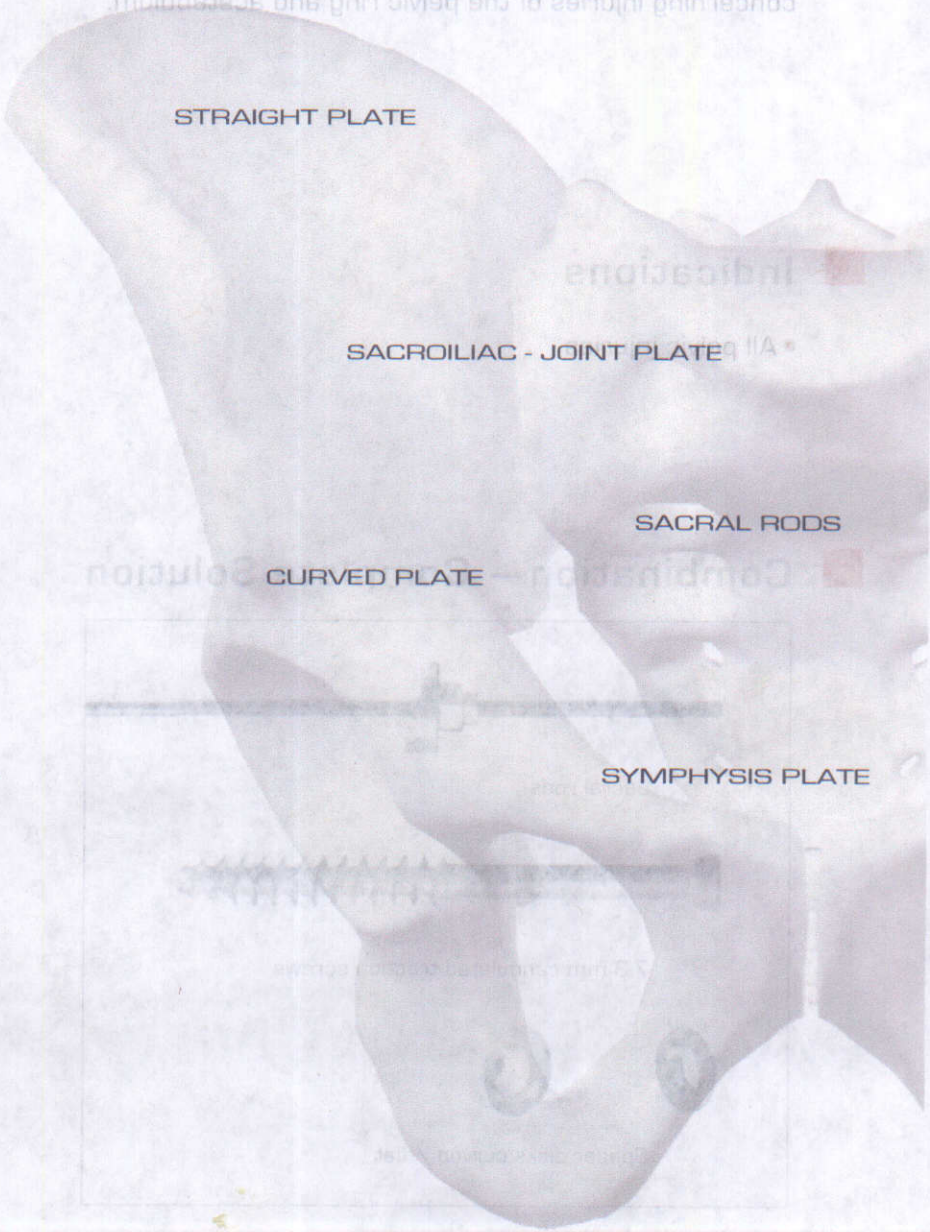
i.t.s. GmbH
IMPLANT-TECHNOLOGY-SYSTEMS

EMERGENCY TEAM FOR BROKEN BONES

PRS

Pelvic Reconstruction System

Sacral Rods



A complete system for the treatment of all injuries to the pelvis and acetabulum

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Pelvic Reconstruction System

Complete system for the treatment for all injuries of the pelvis and acetabulum

In combination with **I.T.S. sacral rods, I.T.S. 7.3 mm cannulated traction screws** [with adjustable thread] and **I.T.S. spacer disks** [flat / curved], there is now a complete solution for all established operative methods concerning injuries of the pelvic ring and acetabulum.

Indications

- All pelvic injuries

Combination – Complete Solution

Sacral rods

7.3 mm cannulated traction screws

Spacer disks curved / flat

Pelvic Reconstruction System

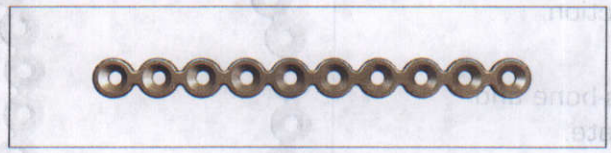
SYMPHYSIS PLATE
PROFILE HEIGHT: 3.5 MM

SIJ-PLATE [CLOSED]
PROFILE HEIGHT: 2.5 MM

SIJ-PLATE [L-SHAPE]
PROFILE HEIGHT: 2.5 MM

CURVED PLATE [RADIUS 88 MM]
PROFILE HEIGHT: 2.5 MM

CURVED PLATE [RADIUS 108 MM]
PROFILE HEIGHT: 2.5 MM



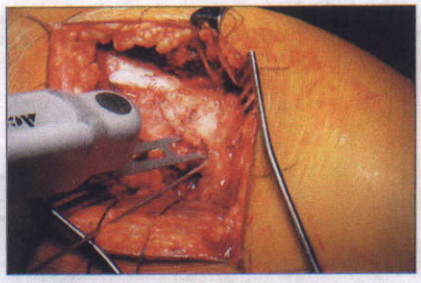
STRAIGHT PLATE
[DORSAL ILIO - ILIAC DISTANCE OSTEOSYNTHESIS]
PROFILE HEIGHT: 3.5 MM

Characteristics

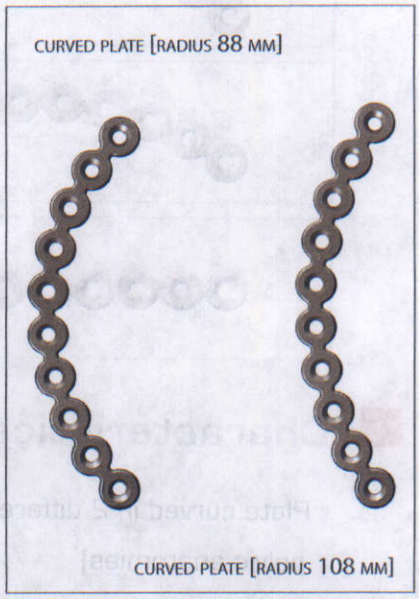
- Plate curved in 2 different degrees - anatomically contoured [for male and female pelvic anatomies]
- Can be anatomically shaped [bending pliers and setting instruments]
- Locking screw arrangement
- Bending templates [to avoid repeated in situ attachment and readjustment]
- Variable angle [+/- 15°] between plate and screw - also in the case of locking screw arrangement
- Material of plate: pure titanium
- Material of screws: TiAL6V4 ELI
- I.T.S. surface treatment [will not grow into bone]
- 3 types of screws can be used

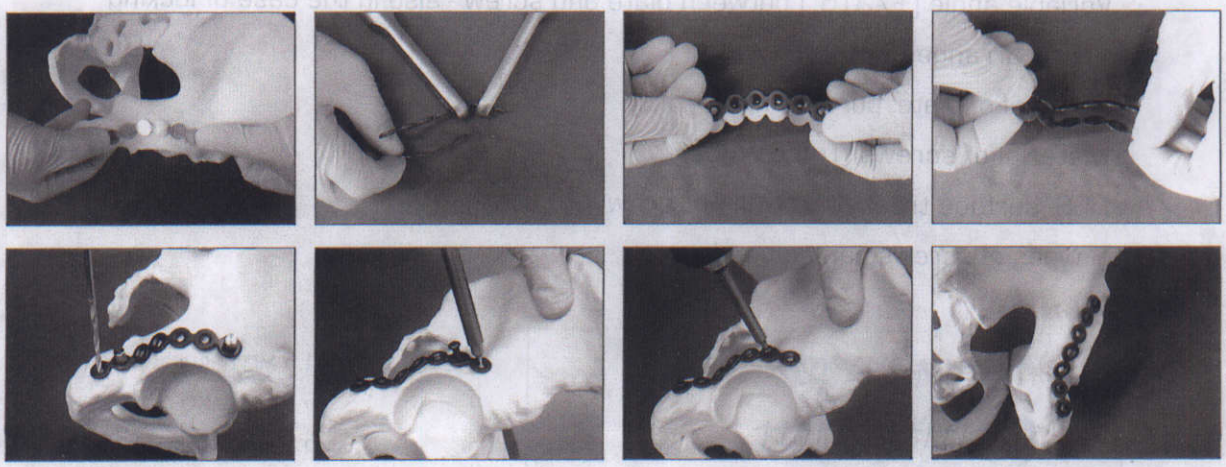
4.5 MM CORTICAL SCREW
5.9 MM CANCELLOUS-BONE SCREW
5.9 MM ANGLE-STABLE CANCELLOUS-BONE SCREW

Application of Acetabular Plate

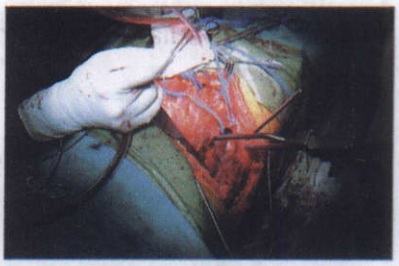


- Access by means of Kocher-Langenbeck approach, possibly using trochanter-flip osteotomy and surgical luxation.
- Reduction and temporary fixation using K-wire.
- Shaping of the bending template.
- Appropriate final adjustment of the plate.
- Application of the plate and temporary fixation using spikes and fluoroscopic or X-ray inspection.
- Finally, insertion of cortical, cancellous-bone and locking screws into the holes of the plate.
- Fluoroscopic or X-ray inspection.
- Drainage of the area and layered closure of the wound [refixation of trochanter major if required].

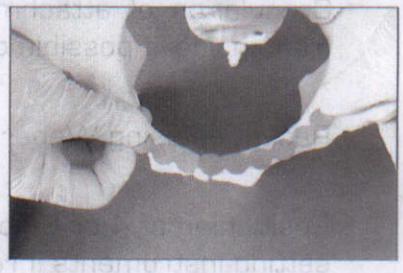




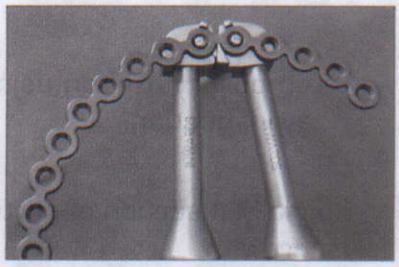
Reconstruction of Anterior Pelvic Ring using Reconstruction Plate



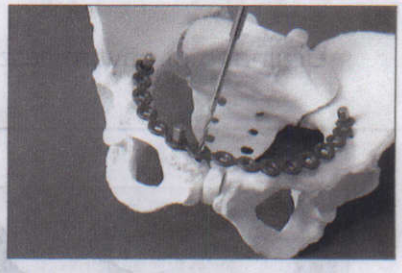
- Ilio-inguinal approach or possibly Stoppa approach.



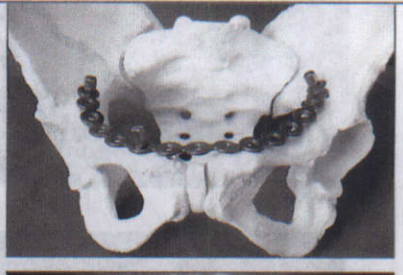
- Reduction using Weber or Jungbluth forceps, Schanz screw and temporary K-wire fixation if required.



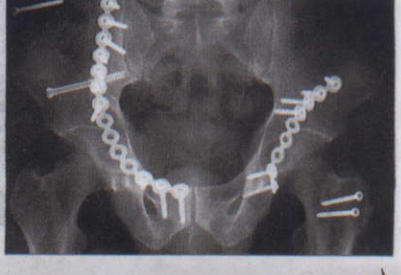
- Attachment and adjustment of appropriate bending template, with fluoroscopic or X-ray inspection if required.



- Adjustment and setting of reconstruction plate on the bending template using setting instruments or bending pliers.

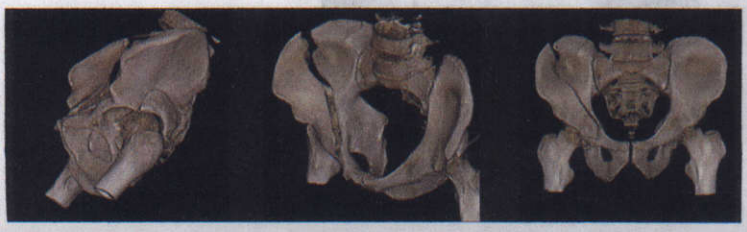


- Attachment of the plate and temporary fixation using spikes and fluoroscopic or X-ray inspection.



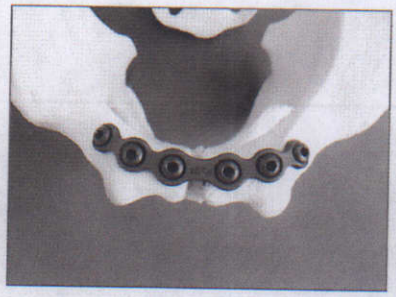
- Finally, insertion of cortical, cancellous-bone and locking screws. Conclude with fluoroscopic or X-ray inspection.

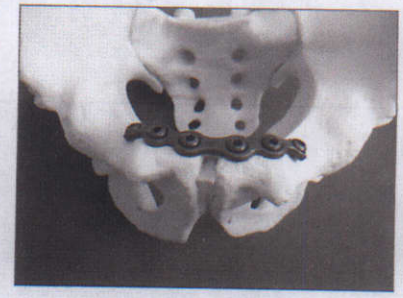
- Drainage, closure of wound.

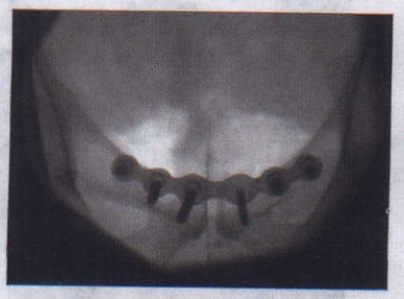


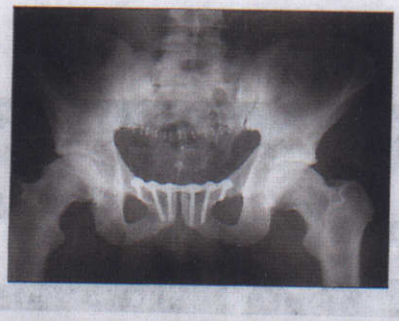
Application of Symphysis Plate

- Lower medial laparotomy [emergency] or Pfannenstiel incision.
- Extra-peritoneal opening of the pelvis minor in the linea alba.
- Crenulation of attachments to the rectus abdominis from inside, if possible do not sever laterally.
- Resection using Weber or Jungbluth forceps.
- Positioning of 4 or 6-hole plate superiorly [adjust using setting instruments if required].
- Temporary fixation using spikes and fluoroscopic or X-ray inspection.
- Finally, insertion of cortical, cancellous-bone and locking screws.
- Drainage of cavum retzii, closure of the wound.



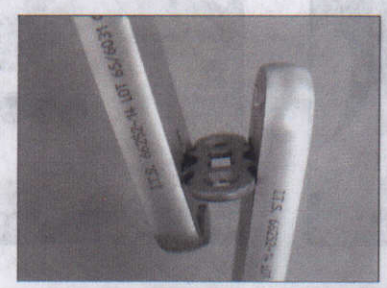


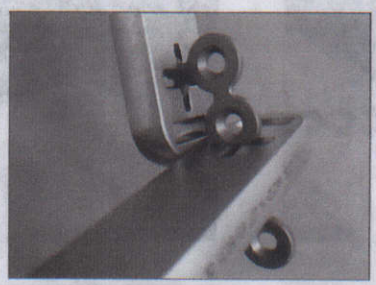


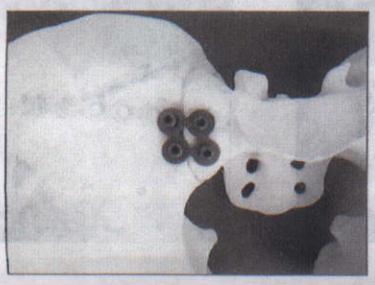


Application of SIJ Plate

- Antero-lateral approach or first window in the context of an ilio-inguinal approach.
- Adjustment of sacroiliac joint with Hohmann retractors.
- Resection using Weber or Jungbluth forceps.
- Adjustment of a double-hole plate or double L-plates.
- Temporary fixation using spikes and fluoroscopic or X-ray inspection.
- Finally, insertion of cortical, cancellous-bone and locking screws.
- Drainage, closure of wound.

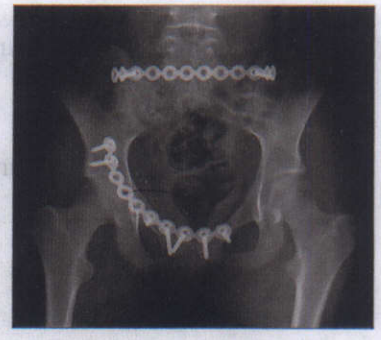


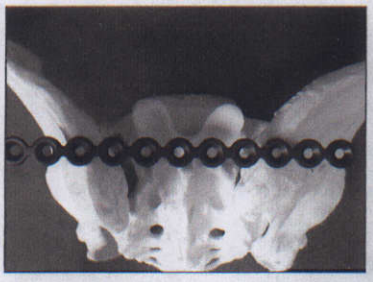


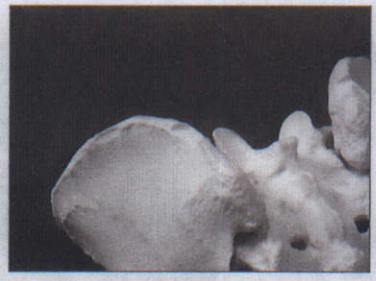


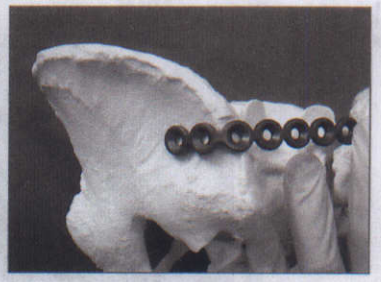
Ilio-Iliac Distance Osteosynthesis

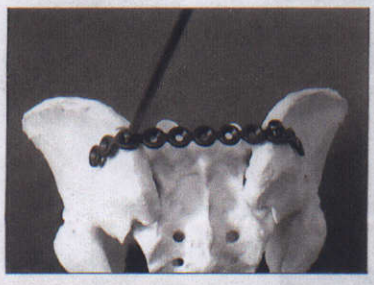
- Approach:
  Bilateral superior 5-cm-long incision from the spina iliaca posterior superior.
- Bilateral exposure of rear iliac crest.
- Reduction using Schanz screw, longitudinal traction on leg, if necessary with the help of reduction forceps.
- Determination of plate length.
- Chisel off plate bearing [approx. 4 mm deep].
- Bend the plate from one side. Push the plate through behind the sacrum. Bend the plate on both sides in situ.
- Adjust plate and insert both screws on iliac crest. Alternate tightening of screws.
- Insert locking screws in both holes of the short side piece of the plate, at the same time making sure that the screwing angle is 10-15° to the plane of the already attached screw on iliac crest [to prevent collision of the screws - this is not a problem when using **I.T.S. locking screws**].
- Drainage, closure of wound.

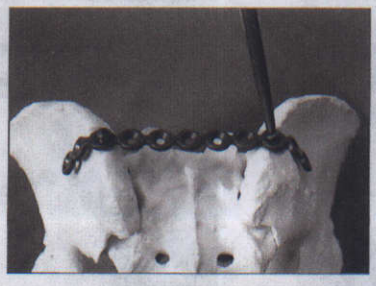


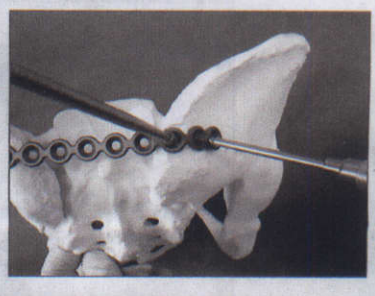












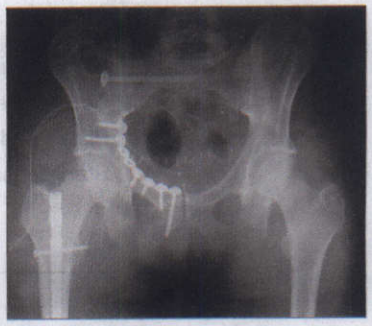
SIJ Screw Fixation

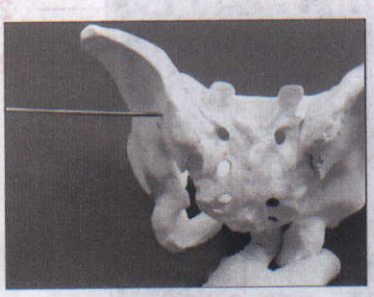
- Approach:
  Abdominal position, lateral stab incision after fluoroscopic inspection.

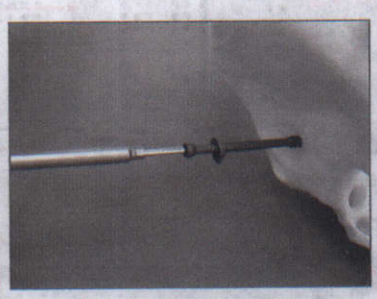
- Position the guide wire under fluoroscopic inspection, alternating in inlet and outlet view or with 2D or 3D navigation.

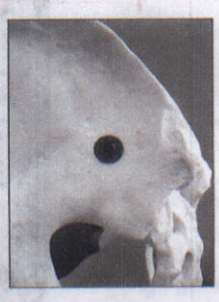
- Determine the length and position cannulated self-drilling 7.3 mm screw with spacer disk. [It is necessary to drill into cortical bone only when bone is very hard].

- Final X-ray inspection and wound closure.

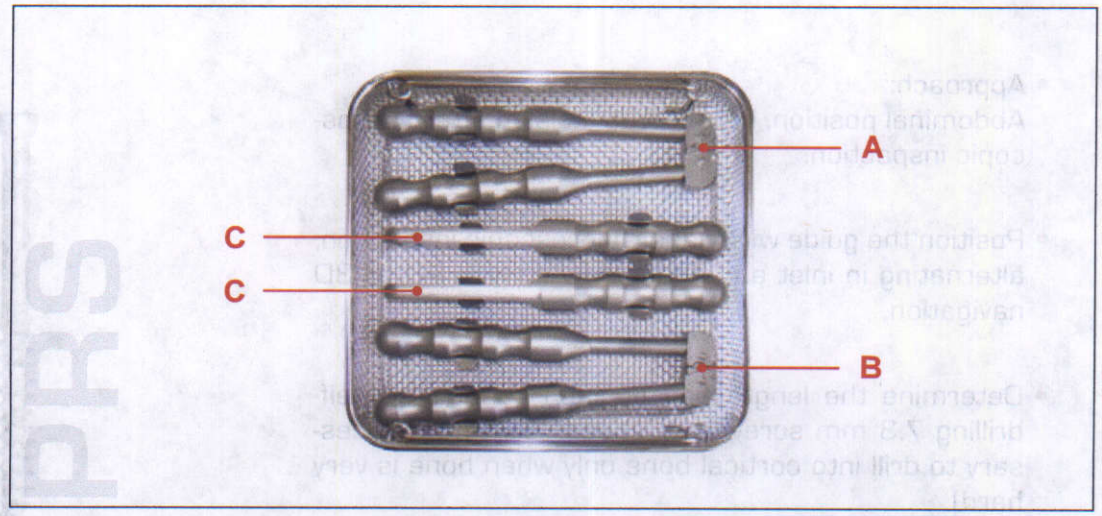






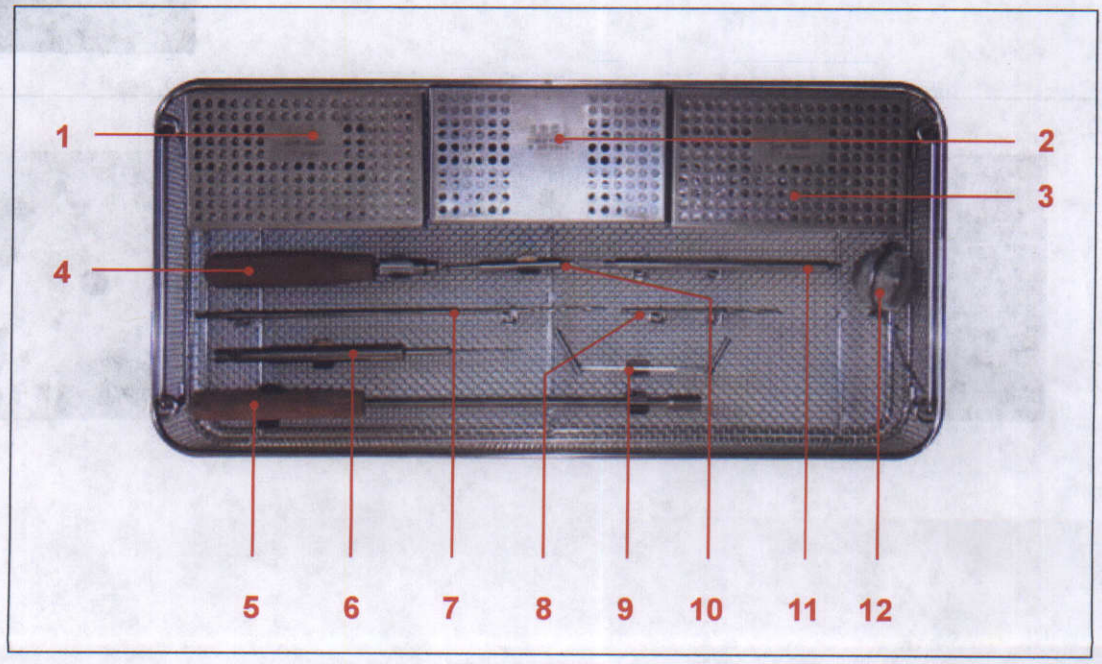


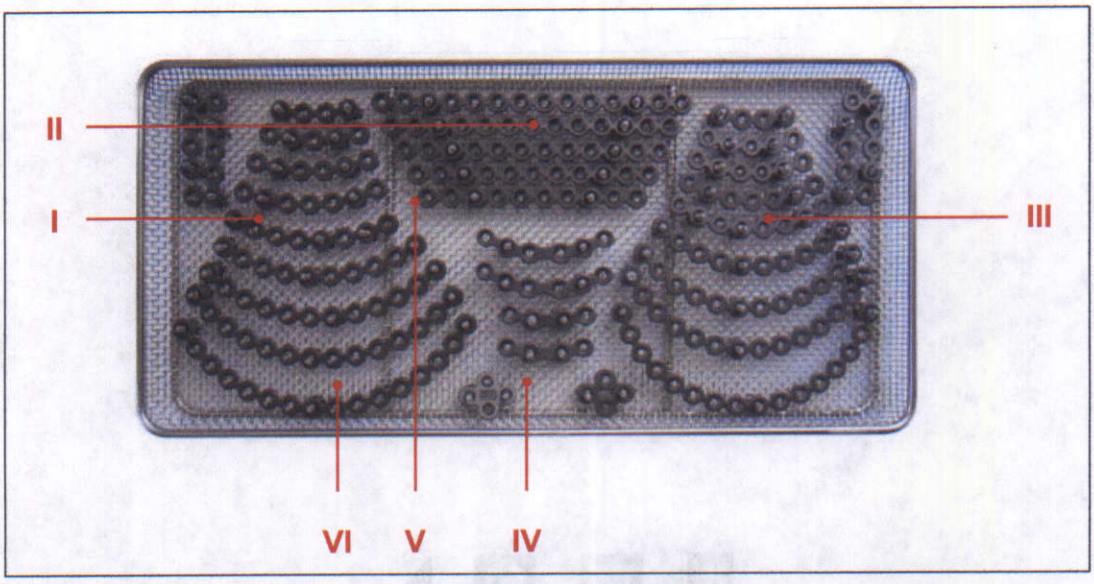
Implants & Instruments



Instruments

		Item no.
A	Bending forceps	66251-1
B	Counter bending forceps	66251-2
C	Plate benders	66252-14
D	Sterilisation case	50168





Instruments

		Item no.
1	Ø 4.5 mm cortical screw 16-60 mm in 4 mm steps 60-80 mm in 5 mm steps	32455-xx
2	Ø 5.9 mm cancellous screw 16-60 mm in 4 mm steps 60-80 mm in 5 mm steps	30591-xx
3	Ø 5.9 mm cancellous stabilisation screw 16-60 mm in 4 mm steps 60-80 mm in 5 mm steps	37592-xx
4	Handle with AO - coupler	53011
5	Socket spanner SW 7 with handle	560701-350
6	Length gauge	59022
7	Ø 3.5mm drill L=280 mm	61353-280
8	Ø 3.5mm drill L=28mm	61353-110
9	Drill guide 2.5 / 3.5 mm	62252
10	Screwdriver shank 3.5 mm selfwedging AO	54353-180SH
11	Screwdriver shank 3.5 mm selfwedging AO	54353-90SH
12	Fixation screws wrench size 7	70301-7
13	Sterilisation case	50169

Implants

		Item no.
I	Straight plate	21181-xx
II	Curved plate R 108 mm	21195-xx
III	Curved plate R 88 mm	21194-xx
IV	Symphysis plate	21161-xx
V	Sacroiliac-joint-plate right	21171-xx
	Sacroiliac-joint-plate left	21172-xx
VI	Sacroiliac-joint-plate closed	21173-xx
VII	Sterilisation case	50167

Bending templates

		Item no.
	Bending templates R 88 mm	67194-xx
	Bending templates R 108 mm	67195-xx

IMPLANT-TECHNOLOGY-SYSTEMS

emergency team for broken bones ®

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I.T.S. Implante Technologie Systeme GmbH

Pelvic Reconstruction System (PRS)
7.3mm Cannulated Screw & Washer System

Surgical Technique

1. Prepare the patient with a general or regional anesthetic to the affected pelvic region area.

2. During the procedure, observe (using x-ray fluoroscopy) the fractured pelvic bone segment area(s). X-ray fluoroscopy observation is required during the entire procedure to ensure proper guide pin placement, proper bone screw depth, and adequate fracture impaction/reduction by the bone screw(s) device.

3. Following fracture reduction under image fluoroscopy control, insert the required size (3.2mm) calibrated guide pin across the pelvis fracture site engaging subchondral bone. If additional fixation is necessary across the fracture site, insert additional calibrated guide pins. Place the multiple guide pins parallel in direction to each other and in such a manner to avoid interference contact if washers are used.

4. Place the calibrated Depth Gauge over the calibrated guide pin and read the actual depth of the pin in the bone. The surgeon may elect to use the appropriate screw 5-10mm less than the Depth Gauge reading depending on screw penetration (ie.; so as not to penetrate into soft tissue).

5. If the cortex is thin or damaged and/or osteoporotic, a flat or curved washer may be placed under the head of the screw to prevent the screw head from being pulled into the cortex. A washer will distribute stress over the cortex of the bone.

6. Using the Gauge 5.0mm Cannulated Screwdriver, drive and seat the self-drilling and self-tapping screw over the guide pin and check the screw depth and fracture impaction/reduction with fluoroscopic x-ray.

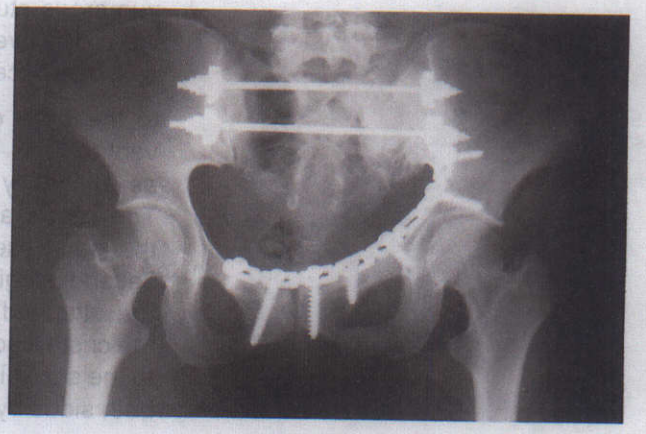
7. Remove the calibrated guide pin.

8. Repeat steps 4 -7 for additional screw fixation across additional pelvic fracture sites and close.

i.T.S. GmbH

Implant-Technology-Systems

SACRAL-RODS



For fixation of posterior pelvic ring instabilities

The operative management of **pelvic ring disruptions has always represented a challenge** to the treating surgeon. The sufficient stabilisation of such an injury requires both a profound knowledge of the anatomy and biomechanics of the pelvis and an understanding of the mechanism of fracture. The chosen technique of a posterior stabilisation depends on the one hand on the kind of fracture, and on the other hand on the personal experience of the individual operator.

Threaded rods as fixators of posterior pelvic ring instability have been well known and well proven for a long time, especially for sacral fractures in all three zones and for detachments of the SI joint (the technique was first described in 1913 by A. Lambotte, but frequent use of sacral rods only started in the 1980s.) The stability of sacral rods has been proved in numerous studies, and in many investigations the rods have been used as a „gold standard" and reference value.

In the case of type C injuries, surgical intervention has first to be ventrally undertaken as a rule by means of plate osteosynthesis. The rear stabilisation is carried out either in the same session or in a quickly following second surgical intervention. The sacral rods are attached by means of the dorsal parts of the crista iliaca dorsal to the sacrum and dorsal to the sacro-iliac joint. The rods are secured on both sides by a nut and locknut.

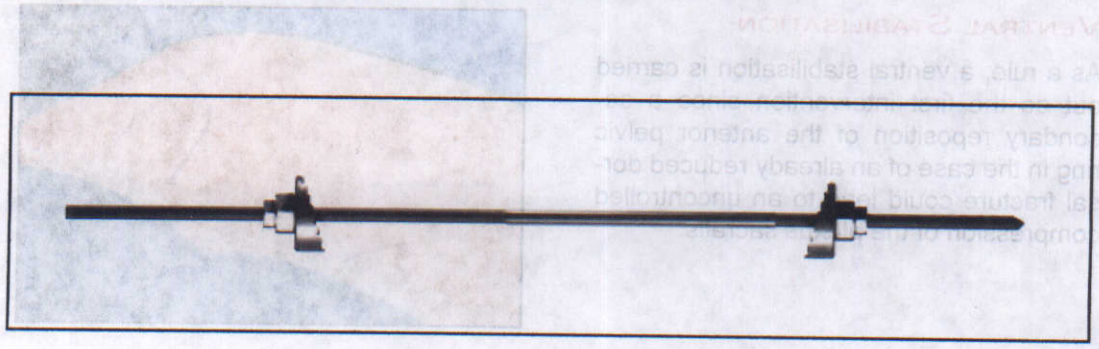
With the present technically perfected armamentarium, the technique has been standardised and considerably simplified. The use of titanium plates imposes no restrictions on postoperative imaging diagnostics.

Properties

- Threaded rods with washers and locknuts for ilio-iliac compression osteosynthesis
- Stepped thread to increase fatigue strength
- Washer: wedge-shaped, ribbed, anatomically contoured
- Stable guiding instrument for simple and safe positioning of threaded rods
- Socket spanner system with AO standard adapter for fast and simple fastening of nuts
- Material: TiAl6V4 ELI
- I.T.S. surface treatment

Advantages

- Simple and safe operative technique
- Low possibility of iatrogenic injury to neural structures
- Low intraoperative X-ray exposure

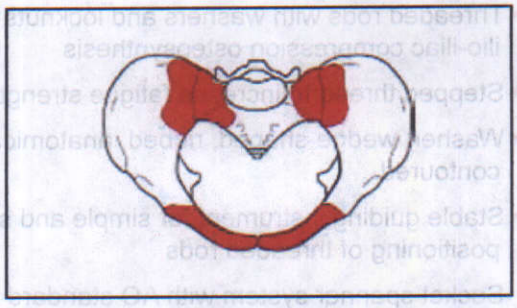


Indications

- Dorsal stabilisation on the posterior pelvic ring for unstable pelvic ring injures type C/AO,

especially in the case of:

- Unstable sacral fractures in all three zones
- Osteo-ligament instabilities of the sacro-iliac joint



Contraindications

- Fractures of the ala of the ilium in the posterior area
- Fractures of the os sacrum in the transforaminal area with CT-verified fractured parts and fragments requiring an open revision and decompression
- For the case that the relevant anatomy appears to preclude a safe positioning of the rods behind the sacral canal (rare)

Description of Surgery

Ventral Stabilisation

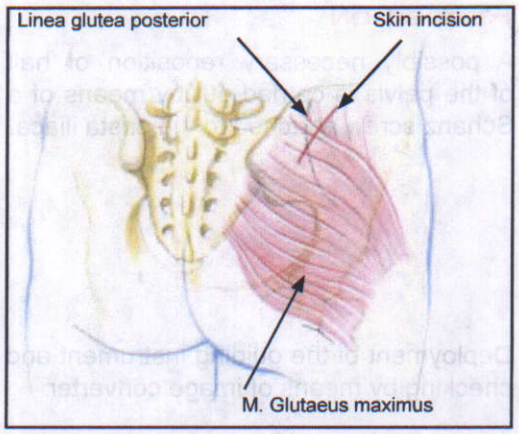
As a rule, a ventral stabilisation is carried out as the first intervention since a secondary reposition of the anterior pelvic ring in the case of an already reduced dorsal fracture could lead to an uncontrolled compression of the plexus sacralis.

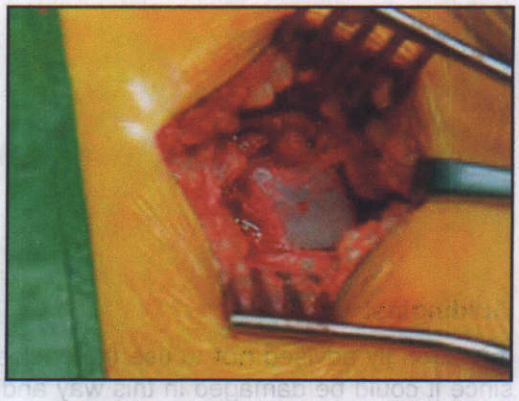
Description of Surgery

Dorsal Stabilisation

Dorsal stabilisation is carried out in the prone position of the patient, usually under full anaesthesia and in the same session.

A curved skin incision is made on both sides lateral to the sacro-iliac joint, from the spina iliaca posterior superior extending cranially with a length of about 5 cm.

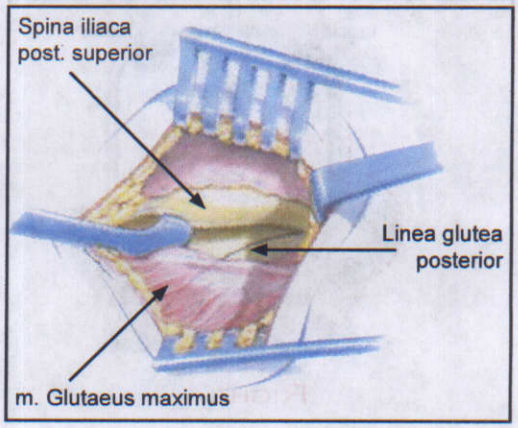




Preparation

Preparation of the subcutaneous fat tissue and carried down to the fascia of the glutaeus maximus muscle.

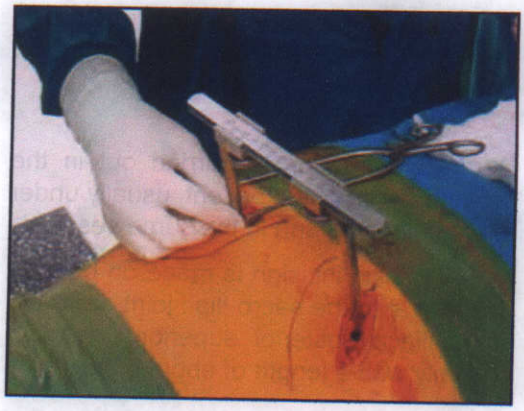
Loosen the musculature from the outer surface of the dorsal os ileum.



Description of Surgery

Reposition

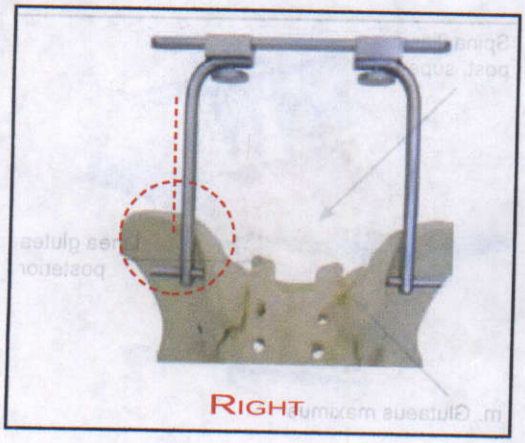
A possibly necessary reposition of half of the pelvis is carried out by means of a Schanz screw attached to the crista iliaca.

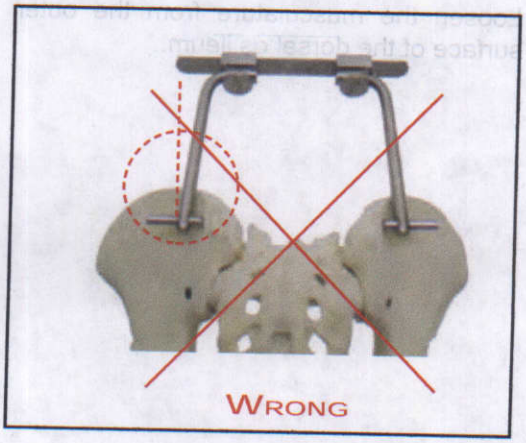


Deployment of the guiding instrument and checking by means of image converter.

Guidinginstrument:

It is strongly advised **not** to use the enclosed guiding device for reducing bone fragments since it could be damaged in this way and prevent a trouble-free attachment of the sacral rods.



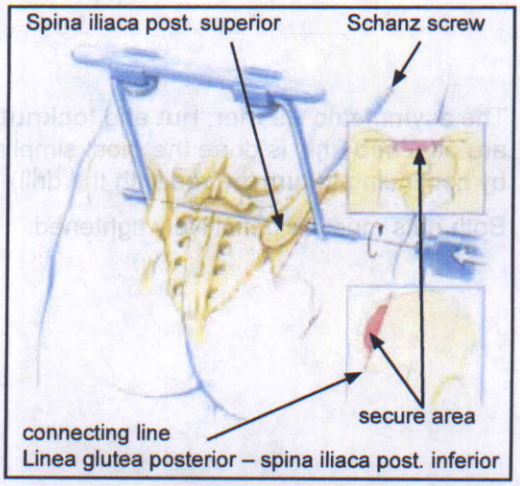


DESCRIPTION OF SURGERY

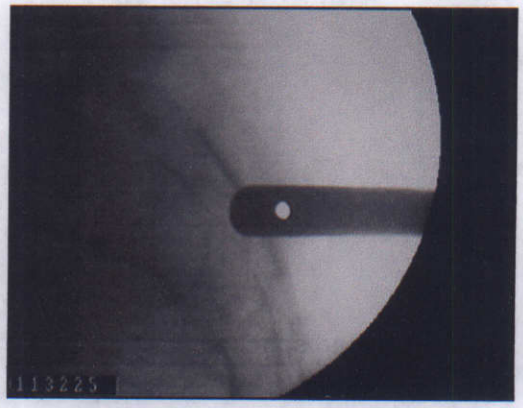
The **linea glutea posterior** acts as the reference point.

The guiding instrument is positioned on a considered line between the origin of the linea glutaea posterior on the iliac crest and the spina iliaca inferior; the drill hole will then lie some 0.5 cm higher.

The **caudal screw** is attached first, and the point of entry is to be chosen such that the rod is at a tangent to the crista centralis of the os sacrum or even perforates it, but at least comes to rest behind the lamina dorsalis of the sacrum.



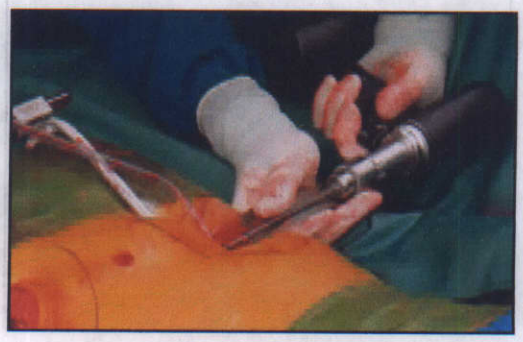
The **guiding instrument** can be swivelled in the caudal direction during radioscopy (otherwise the guiding instrument can become loose due to divergence with the ala of the ileum).



The **threaded rod** is equipped with a drill bit, and young bones should be predrilled. After that, the threaded rod is introduced over the guiding instrument.

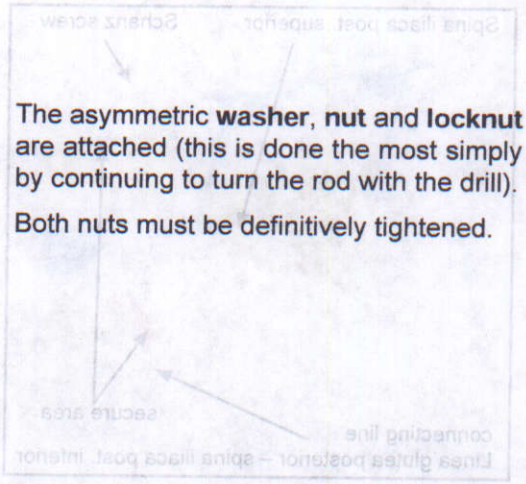
Pre-drilling:

For predrilling we recommend the use of the enclosed drill to achieve a satisfying results.



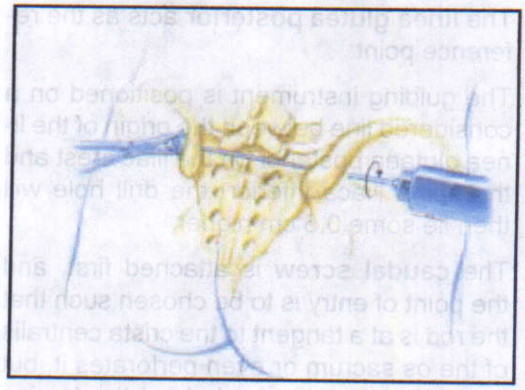
After the **threaded rod** has penetrated the second corticalis of the opposite os ileum, the guiding instrument is dismantled on this side.

DESCRIPTION OF SURGERY

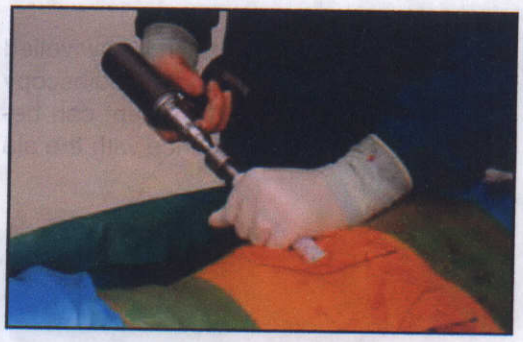


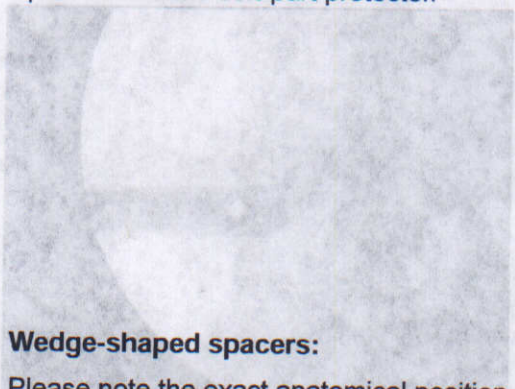
The asymmetric **washer**, **nut** and **locknut** are attached (this is done the most simply by continuing to turn the rod with the drill).

Both nuts must be definitively tightened.



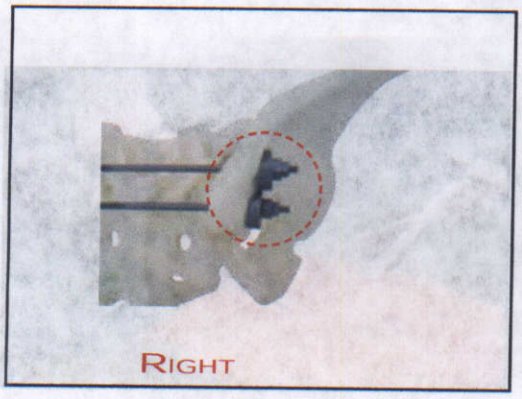
The drill chuck is released, the guiding instrument removed, and the washer is attached as are, successively, both nuts on the second side using the special socket spanner and the soft-part protector.

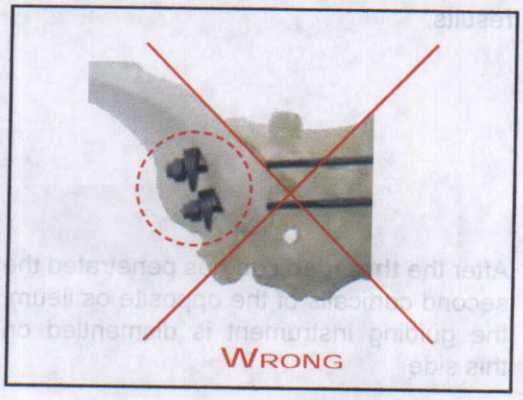




Wedge-shaped spacers:

Please note the exact anatomical position shown here to arrive at the best result.

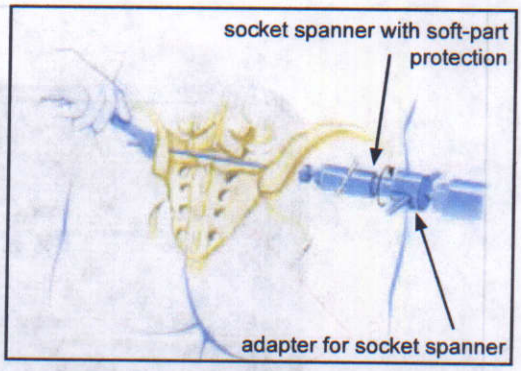


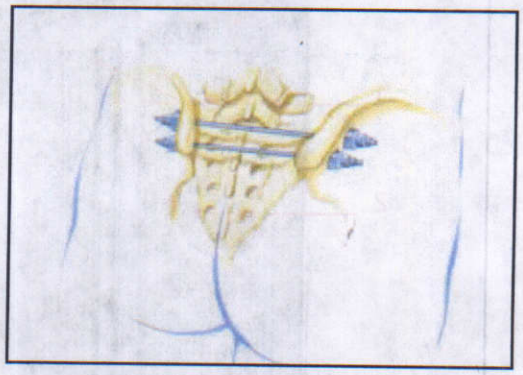


Description of Surgery

The first nut is tightened until the desired compression of the fracture area is reached (care must be taken not to use excessive compression with transforaminal fractures of the sacrum.) Both nuts must be tightened. Remove the excess end using the bolt cutters.

The same procedure is undertaken with the second screw, which is to be positioned some 2 cm cranially to the first screw.





Check

Final check using image converter or X-ray, redon drainage, subsequent closure of the wound.

Postoperative Treatment

Dependent on type of fracture:

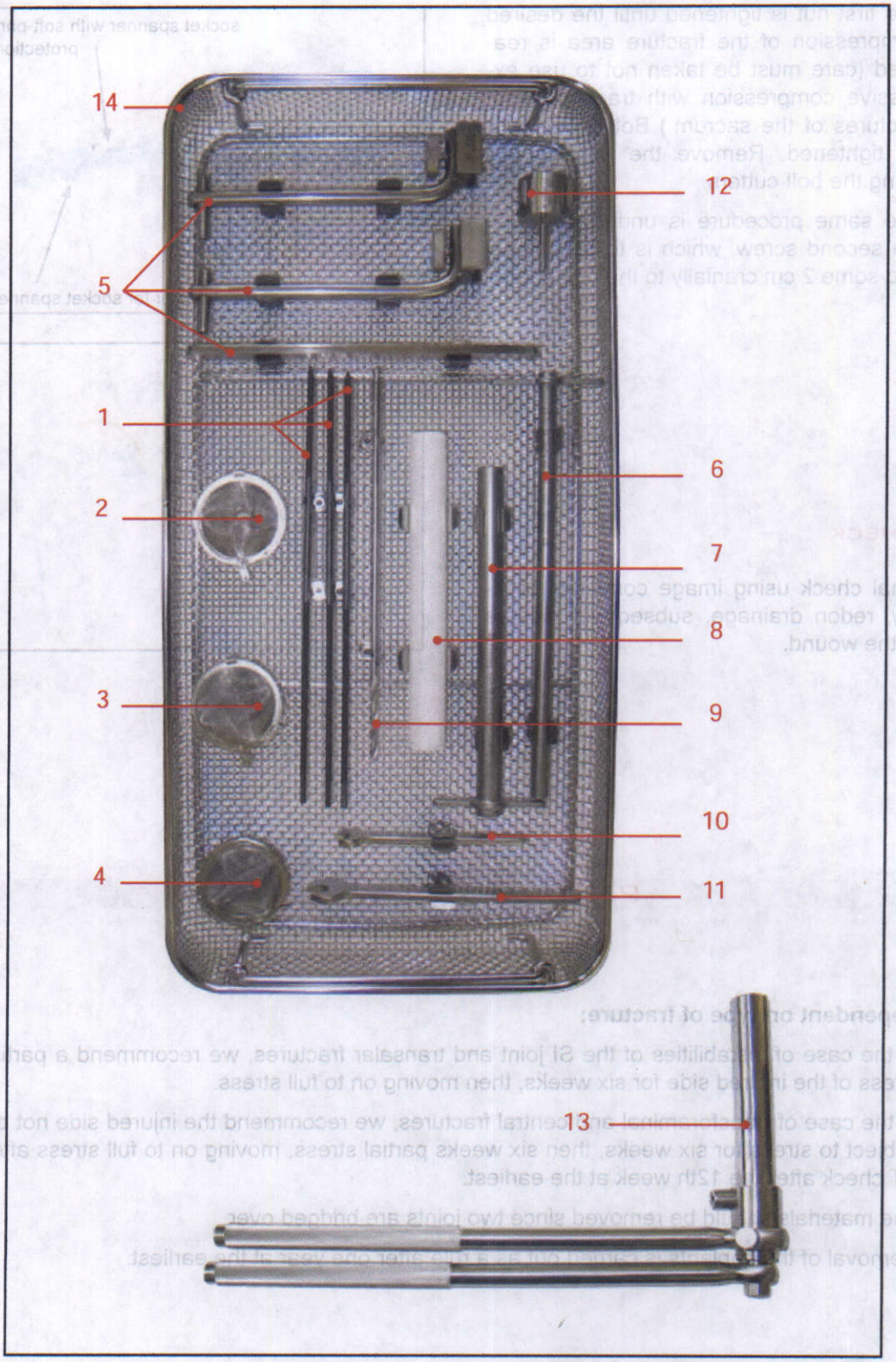
In the case of instabilities of the SI joint and transalar fractures, we recommend a partial stress of the injured side for six weeks, then moving on to full stress.

In the case of transforaminal and central fractures, we recommend the injured side not be subject to stress for six weeks, then six weeks partial stress, moving on to full stress after CT check after the 12th week at the earliest.

The materials should be removed since two joints are bridged over.

Removal of the implants is carried out as a rule after one year at the earliest.

IMPLANTS & INSTRUMENTS



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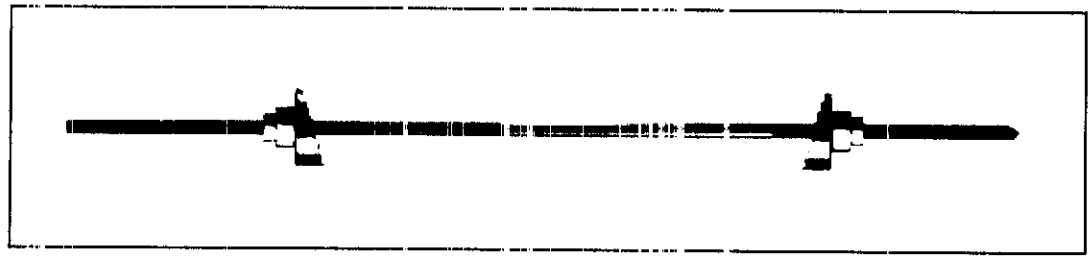
		item no.
1	Threaded Rod	39401-01
2	Washer, wedge-shaped, ribbed (in round sieve	39401-02
3	Counternut , gauge 10 (in round sieve)	39401-03
4	Counternut , gauge 7 (in round sieve)	39401-04

Instruments

		item no.
5	Guiding Instrument	62403
6	Socket Spanner, gauge 7, l=240	56702-240
7	Socket Spanner, gauge 10, l=200	561002-200
8	Tissue Protection Sleeve	62160-180
9	Spiral Drill d=4mm, l=225mm	61403-225
10	Flat spanner, gauge 7	70007
11	Flat spanner, gauge 10	70010
12	AO - Screw Adapter	53400
13	Bolt Cutter	65394
14	Sterilisation Case	50140



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I.T.S. Implantat Technologie Systeme GmbH

Pelvic Reconstruction System (PRS)

Implant and Instrument Listing

PRS Sacral Rod:

IMPLANTS

Part Number	Description
39401-01	Threaded Rod
39401-02	Washer, wedge-shaped, ribbed
39401-03	Counter-nut, gauge 10
39401-04	Counter-nut, gauge 7

INSTRUMENTS

62403	Guiding Instrument
56702-240	Socket Spanner, gauge 7, L=240
561002-200	Socket Spanner, gauge 10, L=200
62160-180	Tissue Protection Sleeve
61403-225	Spiral Drill d=4mm, L=225mm
70007	Flat Spanner, gauge 7
70010	Flat Spanner, gauge 10
53400	AO – Screw Adapter
65394	Bolt Cutter
50140	Sterilization Case

PRS 7.3mm Cannulated SIJ Traction Screw: - **Previously Approved under K060156**

IMPLANTS

Part Number	Size	Description
31734-35	7.3mm x 35mm	7.3mm Cannulated Cancellous Screw, 7.3mmØ, 18mm Variable Th'd Length
31734-40	7.3mm x 40mm	7.3mm Cannulated Cancellous Screw, 7.3mmØ, 20mm Variable Th'd Length
31734-45	7.3mm x 45mm	7.3mm Cannulated Cancellous Screw, 7.3mmØ, 23mm Variable Th'd Length
31734-50	7.3mm x 50mm	7.3mm Cannulated Cancellous Screw, 7.3mmØ, 25mm Variable Th'd Length
31734-55	7.3mm x 55mm	7.3mm Cannulated Cancellous Screw, 7.3mmØ, 28mm Variable Th'd Length
31734-60	7.3mm x 60mm	7.3mm Cannulated Cancellous Screw, 7.3mmØ, 30mm Variable Th'd Length
31734-65	7.3mm x 65mm	7.3mm Cannulated Cancellous Screw, 7.3mmØ, 33mm Variable Th'd Length

Implant and Instrument Listing Continued:

Part Number	Size	Description
31734-70	7.3mm x 70mm	7.3mm Cannulated Cancellous Screw, 7.3mmØ, 35mm Variable Th'd Length
31734-75	7.3mm x 75mm	7.3mm Cannulated Cancellous Screw, 7.3mmØ, 38mm Variable Th'd Length
31734-80	7.3mm x 80mm	7.3mm Cannulated Cancellous Screw, 7.3mmØ, 40mm Variable Th'd Length
31734-85	7.3mm x 85mm	7.3mm Cannulated Cancellous Screw, 7.3mmØ, 43mm Variable Th'd Length
31734-90	7.3mm x 90mm	7.3mm Cannulated Cancellous Screw, 7.3mmØ, 45mm Variable Th'd Length
31734-95	7.3mm x 95mm	7.3mm Cannulated Cancellous Screw, 7.3mmØ, 48mm Variable Th'd Length
31734-100	7.3mm x 100mm	7.3mm Cannulated Cancellous Screw, 7.3mmØ, 40mm Variable Th'd Length
31734-105	7.3mm x 105mm	7.3mm Cannulated Cancellous Screw, 7.3mmØ, 40mm Variable Th'd Length
31734-110	7.3mm x 110mm	7.3mm Cannulated Cancellous Screw, 7.3mmØ, 40mm Variable Th'd Length
31734-115	7.3mm x 115mm	7.3mm Cannulated Cancellous Screw, 7.3mmØ, 40mm Variable Th'd Length
31734-120	7.3mm x 120mm	7.3mm Cannulated Cancellous Screw, 7.3mmØ, 40mm Variable Th'd Length

PRS Washer

36731	7.5mm x 15mm	Washer, Flat, for 7.3mm Cannulated Cancellous, 7.5mm ID x 15.0mm OD
36732	7.5mm x 14mm	Washer, Curved, for 7.3mm Cannulated Cancellous, 7.5mm ID x 14.0mm OD

INSTRUMENTS

59321	Depth Gauge for calibrated Guide Wire
35324-228	3.2mm diameter Guide Wire, Stainless Steel, Threaded Tip, L=228mm
54502-120	Screwdriver, cannulated, Allen Socket Insert, 5.0mm gauge, L=120mm
53032	Handle for Screwdriver, Flat sides
50178	Sterilization Case

PRS Plating and Screw Fixation Systems:

PRS Straight Plate IMPLANT

Part Number	Size	Description
21181-10	10	Straight Plate, 10 Hole
21181-11	11	Straight Plate, 11 Hole
21181-12	12	Straight Plate, 12 Hole
21181-13	13	Straight Plate, 13 Hole
21181-14	14	Straight Plate, 14 Hole

PRS Curved Plate, R=108mm, IMPLANT

Part Number	Size	Description
21195-4	4/R108	Curved Plate, 4 Hole, Radius = 108mm
21195-5	5/R108	Curved Plate, 5 Hole, Radius = 108mm
21195-6	6/R108	Curved Plate, 6 Hole, Radius = 108mm
21195-7	7/R108	Curved Plate, 7 Hole, Radius = 108mm
21195-8	8/R108	Curved Plate, 8 Hole, Radius = 108mm
21195-10	10/R108	Curved Plate, 10 Hole, Radius = 108mm
21195-12	12/R108	Curved Plate, 12 Hole, Radius = 108mm
21195-14	14/R108	Curved Plate, 14 Hole, Radius = 108mm
21195-16	16/R108	Curved Plate, 16 Hole, Radius = 108mm

PRS Curved Plate, R=88mm, IMPLANT

21194-4	4/R88	Curved Plate, 4 Hole, Radius = 88mm
21194-5	5/R88	Curved Plate, 5 Hole, Radius = 88mm
21194-6	6/R88	Curved Plate, 6 Hole, Radius = 88mm
21194-7	7/R88	Curved Plate, 7 Hole, Radius = 88mm
21194-8	8/R88	Curved Plate, 8 Hole, Radius = 88mm
21194-10	10/R88	Curved Plate, 10 Hole, Radius = 88mm
21194-12	12/R88	Curved Plate, 12 Hole, Radius = 88mm
21194-14	14/R88	Curved Plate, 14 Hole, Radius = 88mm
21194-16	16/R88	Curved Plate, 16 Hole, Radius = 88mm

PRS Symphysis Plate IMPLANT

21161-4	4	Symphysis Plate, 4 Hole
21161-6	6	Symphysis Plate, 6 Hole

PRS SacroIliac-Joint L-Shape IMPLANT

21171-5	Left	SIJ-plate, L-shape, 5 Hole, Left
21172-5	Right	SIJ-plate, L-shape, 5 Hole, Right

PRS SacroIliac-Joint Closed IMPLANT

21173-4	Closed	SIJ-plate, Closed, 4 Hole

Implant and Instrument Listing Continued:

PRS 5.9mm Cancellous Bone Screw, Angle Stable, IMPLANT

Part Number	Size	Description
37592-16	5.9mm x 16mm	5.9mm Cancellous Bone Screw, Angle Stable, 16mm Length
37592-20	5.9mm x 20mm	5.9mm Cancellous Bone Screw, Angle Stable, 20mm Length
37592-24	5.9mm x 24mm	5.9mm Cancellous Bone Screw, Angle Stable, 24mm Length
37592-28	5.9mm x 28mm	5.9mm Cancellous Bone Screw, Angle Stable, 28mm Length
37592-32	5.9mm x 32mm	5.9mm Cancellous Bone Screw, Angle Stable, 32mm Length
37592-36	5.9mm x 36mm	5.9mm Cancellous Bone Screw, Angle Stable, 36mm Length
37592-40	5.9mm x 40mm	5.9mm Cancellous Bone Screw, Angle Stable, 40mm Length
37592-44	5.9mm x 44mm	5.9mm Cancellous Bone Screw, Angle Stable, 44mm Length
37592-48	5.9mm x 48mm	5.9mm Cancellous Bone Screw, Angle Stable, 48mm Length
37592-52	5.9mm x 52mm	5.9mm Cancellous Bone Screw, Angle Stable, 52mm Length
37592-56	5.9mm x 56mm	5.9mm Cancellous Bone Screw, Angle Stable, 56mm Length
37592-60	5.9mm x 60mm	5.9mm Cancellous Bone Screw, Angle Stable, 60mm Length
37592-65	5.9mm x 65mm	5.9mm Cancellous Bone Screw, Angle Stable, 65mm Length
37592-70	5.9mm x 70mm	5.9mm Cancellous Bone Screw, Angle Stable, 70mm Length
37592-75	5.9mm x 75mm	5.9mm Cancellous Bone Screw, Angle Stable, 75mm Length
37592-80	5.9mm x 80mm	5.9mm Cancellous Bone Screw, Angle Stable, 80mm Length

PRS 5.9mm Cancellous Bone Screw IMPLANT

Part Number	Size	Description
30591-16	5.9mm x 16mm	5.9mm Cancellous Bone Screw, 16mm Length
30591-20	5.9mm x 20mm	5.9mm Cancellous Bone Screw, 20mm Length
30591-24	5.9mm x 24mm	5.9mm Cancellous Bone Screw, 24mm Length
30591-28	5.9mm x 28mm	5.9mm Cancellous Bone Screw, 28mm Length
30591-32	5.9mm x 32mm	5.9mm Cancellous Bone Screw, 32mm Length
30591-36	5.9mm x 36mm	5.9mm Cancellous Bone Screw, 36mm Length
30591-40	5.9mm x 40mm	5.9mm Cancellous Bone Screw, 40mm Length
30591-44	5.9mm x 44mm	5.9mm Cancellous Bone Screw, 44mm Length
30591-48	5.9mm x 48mm	5.9mm Cancellous Bone Screw, 48mm Length
30591-52	5.9mm x 52mm	5.9mm Cancellous Bone Screw, 52mm Length
30591-56	5.9mm x 56mm	5.9mm Cancellous Bone Screw, 56mm Length
30591-60	5.9mm x 60mm	5.9mm Cancellous Bone Screw, 60mm Length
30591-65	5.9mm x 65mm	5.9mm Cancellous Bone Screw, 65mm Length
30591-70	5.9mm x 70mm	5.9mm Cancellous Bone Screw, 70mm Length
30591-75	5.9mm x 75mm	5.9mm Cancellous Bone Screw, 75mm Length
30591-80	5.9mm x 80mm	5.9mm Cancellous Bone Screw, 80mm Length

Implant and Instrument Listing Continued:

PRS 4.5mm Cortical Bone Screw IMPLANT

Part Number	Size	Description
32455-16	4.5mm x 16mm	4.5mm Cortical Bone Screw, Std., 16mm Length
32455-20	4.5mm x 20mm	4.5mm Cortical Bone Screw, Std., 20mm Length
32455-24	4.5mm x 24mm	4.5mm Cortical Bone Screw, Std., 24mm Length
32455-28	4.5mm x 28mm	4.5mm Cortical Bone Screw, Std., 28mm Length
32455-32	4.5mm x 32mm	4.5mm Cortical Bone Screw, Std., 32mm Length
32455-36	4.5mm x 36mm	4.5mm Cortical Bone Screw, Std., 36mm Length
32455-40	4.5mm x 40mm	4.5mm Cortical Bone Screw, Std., 40mm Length
32455-44	4.5mm x 44mm	4.5mm Cortical Bone Screw, Std., 44mm Length
32455-48	4.5mm x 48mm	4.5mm Cortical Bone Screw, Std., 48mm Length
32455-52	4.5mm x 52mm	4.5mm Cortical Bone Screw, Std., 52mm Length
32455-56	4.5mm x 56mm	4.5mm Cortical Bone Screw, Std., 56mm Length
32455-60	4.5mm x 60mm	4.5mm Cortical Bone Screw, Std., 60mm Length
32455-65	4.5mm x 65mm	4.5mm Cortical Bone Screw, Std., 65mm Length
32455-70	4.5mm x 70mm	4.5mm Cortical Bone Screw, Std., 70mm Length
32455-75	4.5mm x 75mm	4.5mm Cortical Bone Screw, Std., 75mm Length
32455-80	4.5mm x 80mm	4.5mm Cortical Bone Screw, Std., 80mm Length

PRS Plating and Screw Fixation INSTRUMENTS

Part Number	Size	Description
67194-4	4/R88	Bending Template for Curved Plate, Radius = 88mm, 4 Hole
67194-5	5/R88	Bending Template for Curved Plate, Radius = 88mm, 5 Hole
67194-6	6/R88	Bending Template for Curved Plate, Radius = 88mm, 6 Hole
67194-7	7/R88	Bending Template for Curved Plate, Radius = 88mm, 7 Hole
67194-8	8/R88	Bending Template for Curved Plate, Radius = 88mm, 8 Hole
67194-10	10/R88	Bending Template for Curved Plate, Radius = 88mm, 10 Hole
67194-12	12/R88	Bending Template for Curved Plate, Radius = 88mm, 12 Hole
67194-14	14/R88	Bending Template for Curved Plate, Radius = 88mm, 14 Hole
67194-16	16/R88	Bending Template for Curved Plate, Radius = 88mm, 16 Hole
67195-4	4/R108	Bending Template for Curved Plate, Radius = 108mm, 4 Hole
67195-5	5/R108	Bending Template for Curved Plate, Radius = 108mm, 5 Hole
67195-6	6/R108	Bending Template for Curved Plate, Radius = 108mm, 6 Hole
67195-7	7/R108	Bending Template for Curved Plate, Radius = 108mm, 7 Hole
67195-8	8/R108	Bending Template for Curved Plate, Radius = 108mm, 8 Hole
67195-10	10/R108	Bending Template for Curved Plate, Radius = 108mm, 10 Hole
67195-12	12/R108	Bending Template for Curved Plate, Radius = 108mm, 12 Hole
67195-14	14/R108	Bending Template for Curved Plate, Radius = 108mm, 14 Hole
67195-16	16/R108	Bending Template for Curved Plate, Radius = 108mm, 16 Hole
66251-1		Bending Forceps
66251-2		Counter Bending Forceps
66252-14		Plate Benders
53011		Handle
560701-350		Socket Spanner SW 7 with Handle
59022		Length Gauge

PRS Plating and Screw Fixation INSTRUMENTS Continued:

Part Number	Size	Description
61353-280		3.5mm Drill, L = 280mm
61353-110		3.5mm Drill, L = 110mm
62252		Drill Guide 2.5/3.5mm
54353-180SH		Screwdriver SW 3.5mm
54353-90SH		Screwdriver SW 3.5mm
70301-7		Fixation Screws SW 7
50167		Sterilization Case (for Implants)
50168		Sterilization Case (for Bending Forceps, etc.)
50169		Sterilization Case (for Instrumentation)

Section V: Intended Uses/Indications

The ***intended use*** of the I.T.S. Pelvic Reconstruction System (PRS) is to stabilize one or more pelvic bone fractures in the pelvic ring area of the pelvis of an adult or pediatric patient which include the use of the following pelvic fracture fixation systems.

Indications for use of the I.T.S. PRS Low Profile - Multiple Type - Pelvic Plating System include:

1) Fracture reconstruction of the acetabulum, sacrum, illium, and entire pelvic ring,
2) Revision surgery of pseoduarthroses, non-unions and mal-unions,
3) Ilio-Iliac distance osteosynthesis,
4) Osteotomies,
5) Arthrodesis,
6) Sacroiliac joint dislocations, and
7) Symphysis pubis disruptures

Indications for use of the I.T.S. PRS Sacral Rod System include:
1) Fixation of fractures of the posterior pelvis,
2) Fixation of fractures of the posterior iliac spine,
3) Fixation of fractures of the posterior inferior iliac spine,
4) Dorsal stabilization of the posterior pelvic ring for unstable pelvic ring injuries,
5) Fixation of sacral fractures, and
6) Fracture dislocations of the sacro-iliac joint

Indications for use of the I.T.S. PRS 7.3mm Cannulated SIJ Traction Screw & Washer include fracture fixation of pelvic bone fractures where indicated and for periacetabular osteotomies.

for Δ see Section 17. RPJ 12/22/2006
The system ~~is not intended for spinal use.~~

Contraindications for use include active infection near the fracture site, skeletally immature patients, severe osteoporosis or inadequate bone stock, fractures that cannot be acceptably reduced by traction alone, foreign body (material) sensitivity, long delay after injury, and patients with mental or neurological conditions who are unwilling or incapable of following postoperative care instructions.

Contraindications for the sacral rod also include:

1) Fractures of the ala of the ilium in the posterior area,

2) Fractures of the os sacrum in the transforaminal area with CT-verified fractured parts and fragments requiring an open revision and decompression, and

3) For the case that the relevant anatomy appears to preclude a safe positioning of the rods behind the sacral canal.

Section VI: Device Description

The I.T.S. Pelvic Reconstruction System (PRS) encompasses a number of fracture fixation subsystems (multiple pelvic plate designs, sacral threaded rod, and cannulated screw & washer) to make available the necessary implant hardware to the physician in facture fixation and reconstruction of pelvic ring fractures in the pelvis.

The I.T.S. PRS *Low Profile – Multiple Type – Pelvic Plating System* consists of the following plate types: 1) A Straight Plate at a 4.0mm thickness with 10 to 14 hole length sizes, 2) A Curved Plate with a 108mm radius at a 2.5mm thickness with 4 to 16 hole length sizes, 3) A Curved Plate with a 88mm radius at a 2.5mm thickness also with 4 to 16 hole length sizes, 4) A Symphysis Plate at a 4.0mm thickness in both a 4 & 6 hole size, 5) A SacroIlliac-Joint (SIJ) L-Shaped Plate at a 2.5mm thickness in a left and right 5 hole size, and 6) A SIJ Closed Plate at a 2.5mm thickness in a 4 hole size. All plate designs are low profile in thickness, made from CP Titanium for easy 3-Dimensional contouring to the pelvic anatomy, and are smooth and rounded to reduce any soft tissue irritation. The Pelvic Plating System also encompasses a number of cancellous (5.9mm Cancellous standard compression & 5.9mm Cancellous Locking Screws) and cortical (4.5mm standard compression screw) screw types and length sizes to accomodate the bone reconstruction and fixation requirements for various 'indications of use' with all multiple type Pelvic Plate designs. All bone screws are pre-drilling ad self-tapping in design and manufactured from high strength 6-4 Alloyed Titanium. All components

(plates & screws) have a TIODIZE II surface treaatment to improve surface material hardness and enhance biocompatibility to adjacent tissue.

The design intent of PRS Pelvic Plating System is to introduce locking bone screws into both the bone and bone plate and provide stabilization to the fracture or osteotomy site. This concept prevents any loosening of the screw(s) from the plate and gives a solid construct of screw-to-plate across the fracture site. The bone screws are comprised of a harder and high strength 6-4 Alloy Titanium material where the outer head portion of the screw is configured with a 'tapered thead' and introduced (self-tapping) into the bone mass through the countersunk portion of the receiving hole in the softer material CP Titanium plate. The head-thread engages into the countersunk plate hole and locks into place within the plate at a pre-determined angle of up to 20°. This concept of the screw locking into the plate is comparable to other plating systems such as the I.T.S. Volar Radius Plate (**K033756**) and the Hand Innovations Volar Radius Plate (**K002775**).

The I.T.S. PRS Sacral Rod System consists of a threaded pin, wedge-shaped washer(2ea.), and nut/locknut(2ea.) design. One end of the threaded pin has a trocar point for guiding the pin if the guiding instrument is not used. The assembled unit is used to stabilize ilio-iliac posterior pelvic ring disruption injuries. All components are manufactured from high strength 6-4 Alloyed Titanium material and have the TIODIZE II surface preparation, again for increased material surface hardness and biocompatibility.

510(k) Submission
I.T.S. Implantat-Technologie-Systeme GmbH
Pelvic Reconstruction System (PRS)

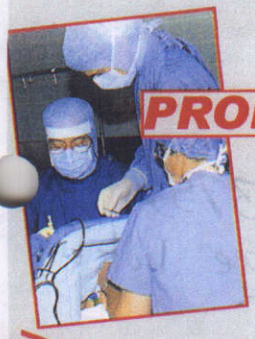
The I.T.S. PRS 7.3mm Cannulated SIJ Traction Screw & Washer is a pre-drilling, self-tapping, and back-tapping (if removal is necessary) screw design for guided reduction of pelvic bone fractures. The system uses a 3.2mm calibrated guide wire for precise positioning of the cannulated screw across the pelvic bone fracture when used in conjunction with x-ray imaging. Washers (flat & curved) are available for use with the screw when encountering thin cortex or osteopenic bone – where the screw head may break through. All 7.3mm Cannulated Screws and Washers are manufactured from high strength 6-4 Alloyed titanium and have the TIODIZE II surface preparation for increased material surface hardness and biocompatibility.

All Pelvic Reconstruction fracture fixation Systems (PRS) have a full set of instrumentation for use with each system.

Marketing brochures are enclosed in this section to show this screw plate locking system design concept from the referenced 510k's. A surgical technique and listing of the implant system with instrumentation is enclosed in ***Section IV*** of this application.

Information regarding the I.T.S. PRS System is disclosed in the attached brochure (*entitled: PRS & Sacral - Rods*) within ***Section IV*** of this submission. The brochure describes in detail the Design Properties, Materials, Indications, and **listing** of *ALL size components for both implants and instrumentation.* Also, within Section IV is the surgical technique describing use of all devices.

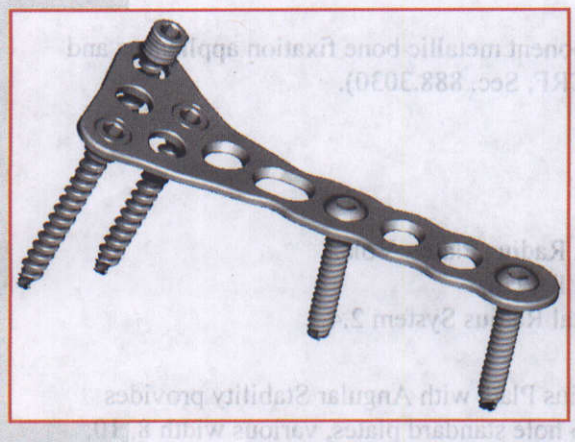
Drawings of ALL implant components (with all sizes) within the system is enclosed in this section.



Volar radius plate with angular stability

PROPERTIES

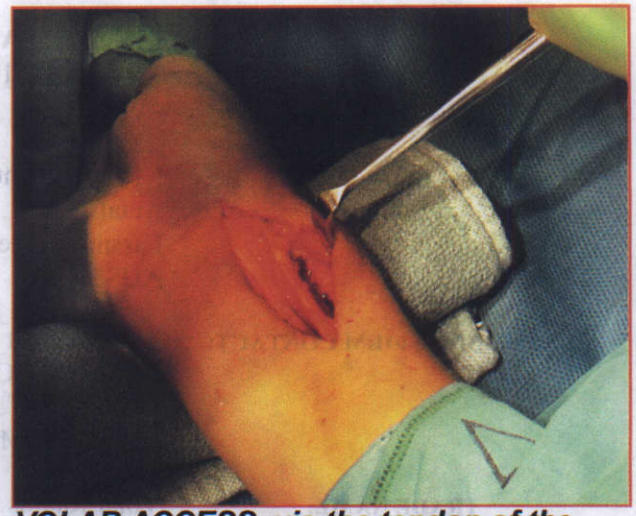
- Angular stability between screws and plate
- Free selection of screw angle to the normal of the plate
- Left and right versions
- Profile height: only 1.5 mm
- Anatomical shape
- Angle-stable 3.5mm spongiosa stabilization screw of 14 - 30mm, in 2mm steps
- Plate material: pure titanium
- Screw material: TiAl6V4
- Surface treatment



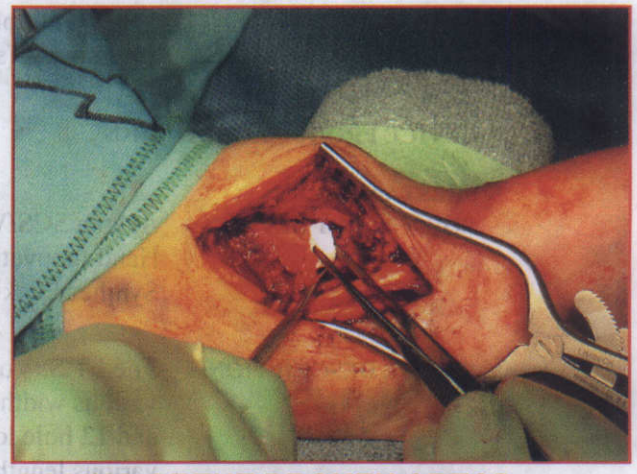
INDICATIONS

- Complex intra-articular fractures of the distal radius
- Complex extra-articular fractures of the distal radius
- Osteotomies of the distal radius

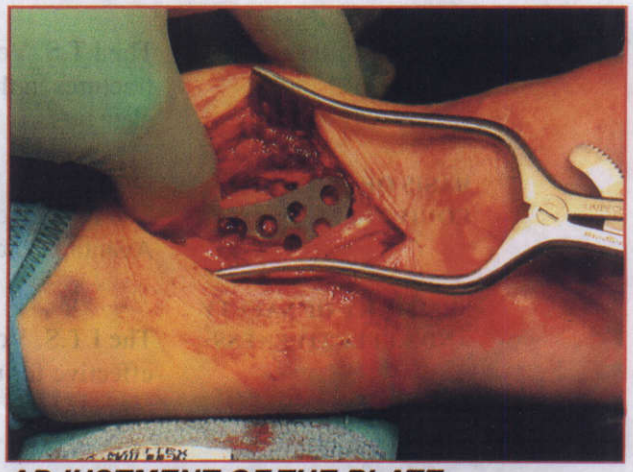
SURGICAL TECHNIQUE



VOLAR ACCESS via the tendon of the flexor carpi radialis muscle
Separation of the transverse carpal ligament.
Open reduction



FILLING OF THE BROKEN AREAS
with bone substitute (e.g. Tutobone®)



ADJUSTMENT OF THE PLATE
to the anatomy

Section XII: 510(k) Summary of Safety and Effectiveness

FEB - 6 2004

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

K033756
page 1 of 1

NAME OF FIRM: I.T.S. Implantat-Technologie-Systeme GmbH.
Autal 28.
Lassnitzhoehe A – 8301
AUSTRIA

510(k) FIRM CONTACT: Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372

TRADE NAME: Volar Radius Plate with Angular Stability

COMMON NAME: Fracture Fixation Plating system for fracture fixation of the end of long bones

CLASSIFICATION: Single/multiple component metallic bone fixation appliances and accessories (see 21 CRF, Sec. 888.3030).

DEVICE PRODUCT CODE: HRS

SUBSTANTIALLY EQUIVALENT DEVICES: Avanta SCS/V Distal Radius Plate - Volar
Hand Innovations DVR Plate
Synthes Locking Distal Radius System 2.4

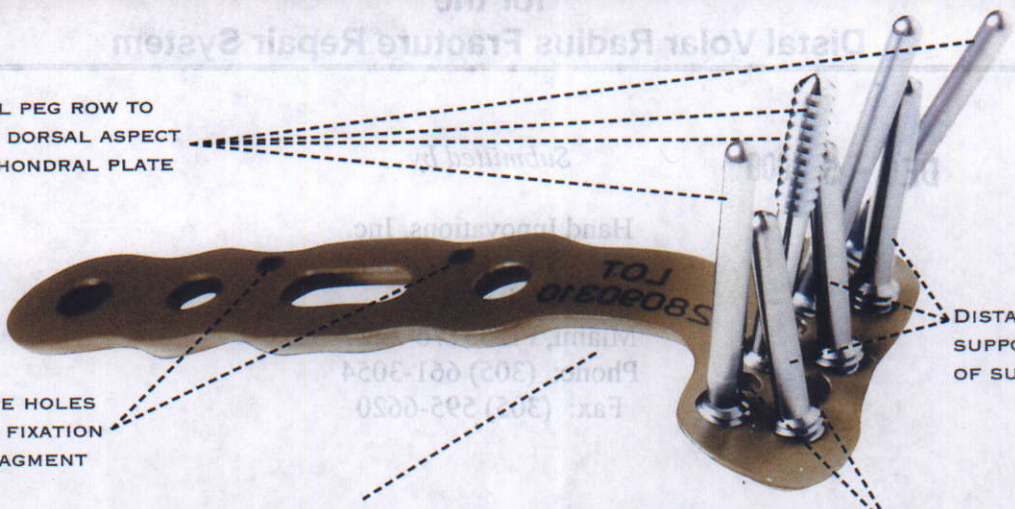
DEVICE DESCRIPTION: The I.T.S. Volar Radius Plate with Angular Stability provides various width 4 and 6 hole standard plates, various width 8, 10, and 12 hole long plates, various length stabilization screws, and various length cortical fixation screws. The volar radius plates are made from CP Titanium according to ASTM F 67-00 and the screws are made from 6-4 Alloyed Titanium according to ASTM F 136-98.

INTENDED USE: The I.T.S. Volar Radius Plate is used to stabilize distal radius fractures in the wrist with an accurate retention of articular fracture elements.

BASIS OF SUBSTANTIAL EQUIVALENCY: The I.T.S. Volar Radius Plate is substantially equivalent to the Avanta, Hand Innovations, and Synthes fracture plating systems

SUMMARY OF SAFETY AND EFFECTIVENESS: The I.T.S. Volar Radius Plate system is shown to be safe and effective for use in fracture fixation of the distal radius in the wrist.

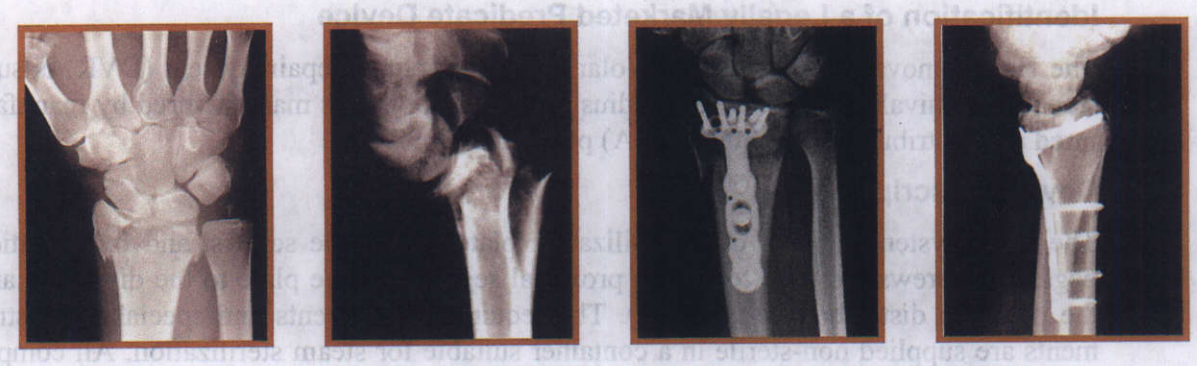
THE ONLY VOLAR PLATE DESIGNED FOR DORSAL FRACTURES

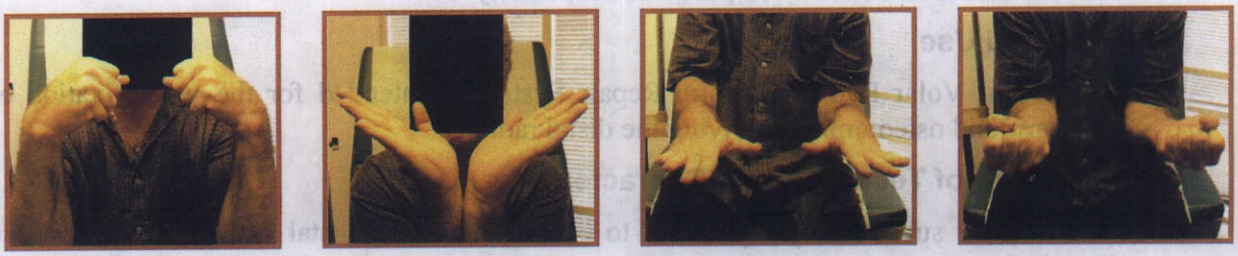


DISTAL FIXATION OPTIONS:

- SMOOTH PEGS OFFER THE STRONGEST SUPPORT
- THREADED PEGS TO LAG DORSAL FRAGMENTS
- CANCELLOUS SCREWS FOR VOLAR FRACTURES

DISTAL K-WIRE HOLES FOR TEMPORARY FIXATION AND PLATE ALIGNMENT TO DISTAL FRAGMENT





FUNCTIONAL RESULTS

HAND INNOVATIONS

8905 SW 87TH AVENUE, SUITE 220, MIAMI, FLORIDA 33176
PHONE (305) 412-8010 (800) 800-8188 FAX (305) 412-8060
WWW.HANDINNOVATIONS.COM

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Summary of Safety and Effectiveness As Required by 807.92(c) for the Distal Volar Radius Fracture Repair System

DEC - 5 2000

Submitted by

Hand Innovations, Inc.
8905 SW 87th Avenue
Suite 100
Miami, FL 33176-2227
Phone: (305) 661-3054
Fax: (305) 595-6620

Contact Person: Al Weisenborn

Device Trade Name: Distal Volar Radius Fracture Repair System
Common Name: Distal Volar Radius Locking Plate with pegs and screws
Classification Name: Single/multiple Component Metallic Bone Fixation Appliances and Accessories, per § 888.3030

Identification of a Legally Marketed Predicate Device

The Hand Innovations, Inc. Distal Volar Radius Fracture Repair System (DVR) is substantially equivalent to the Distal Radius Plate System that is manufactured by manufactured and distributed by Synthes (USA) pursuant to K982732.

Device Description

The DVR system consists of a stabilization plate, four bone screws, and four fixation pegs. The screws are used to fix the proximal segment of the plate to the diaphysis and the pegs the distal bone fragment(s). The required components and specialized instruments are supplied non-sterile in a container suitable for steam sterilization. All components and instruments may be purchased separately.

Intended Use

The Distal Volar Radius Fracture Repair System is intended for the volar fixation of fractures and osteotomies involving the distal radius.

Summary of Technological Characteristics

The DVR is substantially equivalent to equivalent to the Distal Volar Radius Fracture Repair System that is manufactured by manufactured and distributed by Synthes (USA) pursuant to K982732. This has been demonstrated through a 15 point comparison of technological characteristics.

Summary of Performance Data

A dimensional analysis of the DVR fracture repair system components met design requirement. Tensile strength performance characteristics of the DVR and predicate device were tested; the DRV was found to meet or exceed the measured performance characteristics of the predicate device.

Conclusion

The DVR has been demonstrated to be equivalent to the Distal Radius Plate System that is by manufactured and distributed by Synthes (USA) pursuant to K982732, Inc. by bench testing of both devices and comparison of technological characteristics.

The tissue/bone contact material of the device have been carefully selected for its long history of biocompatibility. The material meets the requirements of a recognized consensus standard for implantable orthopedic material.

The DVR was designed utilizing design controls compliant with the Quality System Regulation. The DVR will be manufactured per specifications and good manufacturing practices that ensure the device is safe and effective for its intended use.

PRS Sacral Rod System Drawings

CONFIDENTIAL

b(4) Engineering Design

b(4) Engineering Design

b(4) Engineering Design

b(4) Engineering Design

PRS 7.3mm Cannulated SIJ Traction Screw System Drawings

CONFIDENTIAL

b(4) Engineering Design

b(4) Engineering Design

b(4) Engineering Design

PRS Pelvic Plating System Drawings

CONFIDENTIAL

b(4) Engineering Design

b(4) Engineering Design

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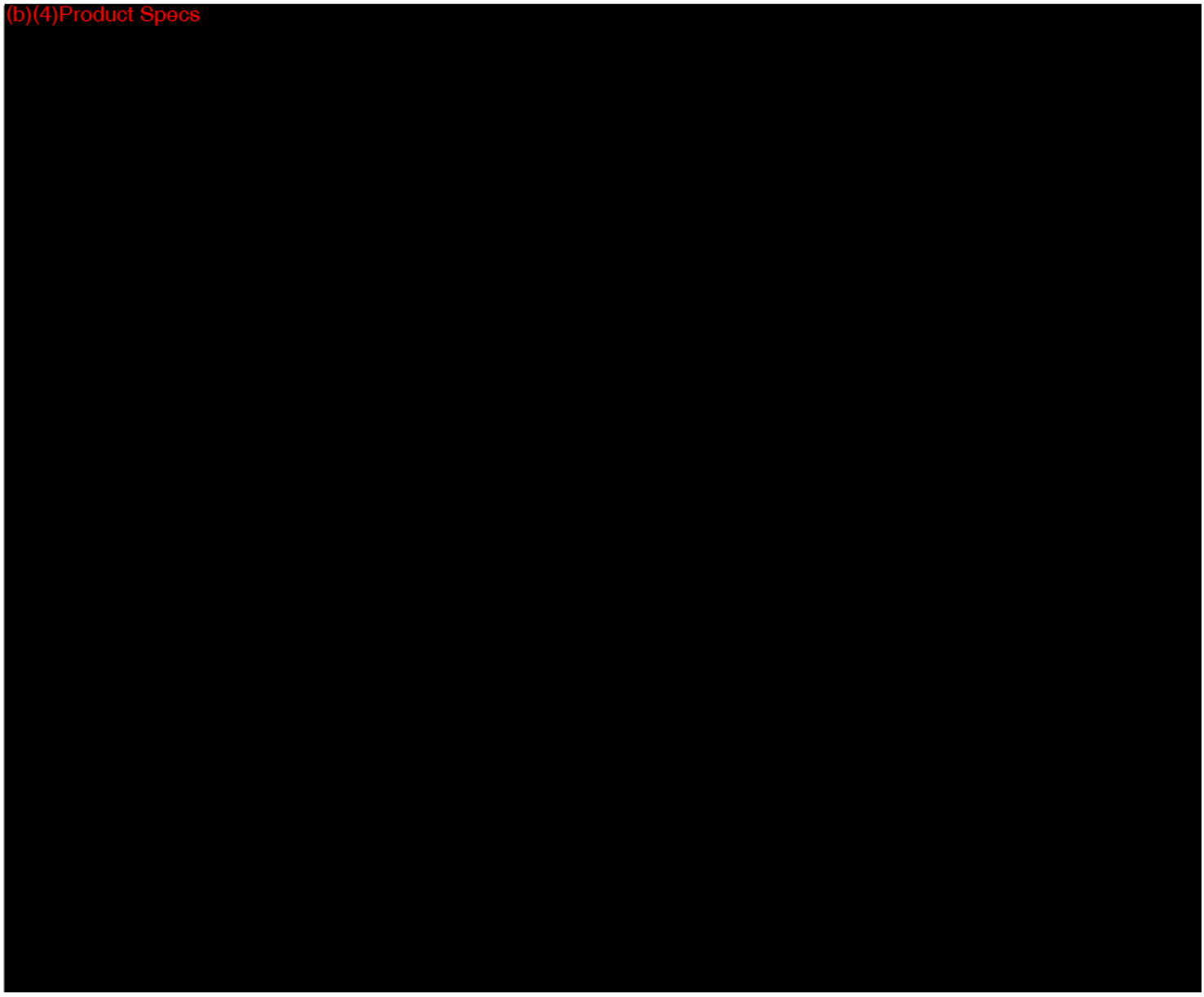
Section VII: Materials

(b)(4)Product Specs



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Section VIII: Testing Information

Section VII in this submission produces the mechanical/chemical testing of the material as stipulated in the ASTM Specifications F 136 & F 67.

Enclosed in this section is an Engineeering Rationale disclosing information as to why mechanical torque and dynamic bend testing is not necessary for the I.T.S. Pelvic Reconstruction System (PRS) due to similarities to predicate devices. Enclosed with this rationale are marketing references, dimensional and material information of the predicate device(s), and 510(k) Summary Statements of the predicate devices.

b(4) Testing

b(4) Testing

b(4) Testing

b(4) Testing

b(4) Testing

(b)(4)Analysis Specs

(b)(4)Analysis Specs

(b)(4)Analysis Specs

(b)(4)Analysis Specs

K000120

SYNTHES®

AUG 2 4 2000

3.0 Summary of Safety and Effectiveness Information

SPONSOR:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Angela Silvestri
DEVICE NAME:	Synthes Sacral Bar System
CLASSIFICATION:	21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener.
PREDICATE DEVICES:	Zimmer Threaded Sacral Rod Synthes Threaded Bolt
DEVICE DESCRIPTION:	The Synthes Sacral Bar System consists of a threaded bar, washers, and nuts. The bars are fully threaded. One end of the bar has a trocar point to guide the bar through pre-drilled holes. The bars are available in lengths ranging from 120 to 260 mm, in 10 mm increments. The washers that are used with this system are oval shaped and are designed to slide freely along the bars. Both rounded and straight nuts are provided with this system; the rounded nuts mate with the washers to create compression, while the straight nuts are then added to wedge against the rounded nuts to maintain compression.
INTENDED USE:	The Synthes Sacral Bar System is intended for fixation of fractures of the posterior pelvis, in areas of the posterior superior iliac spine and posterior inferior iliac spine, for sacral fractures and fracture-dislocations of the sacro-iliac joint.
MATERIAL:	Implant quality stainless steel.

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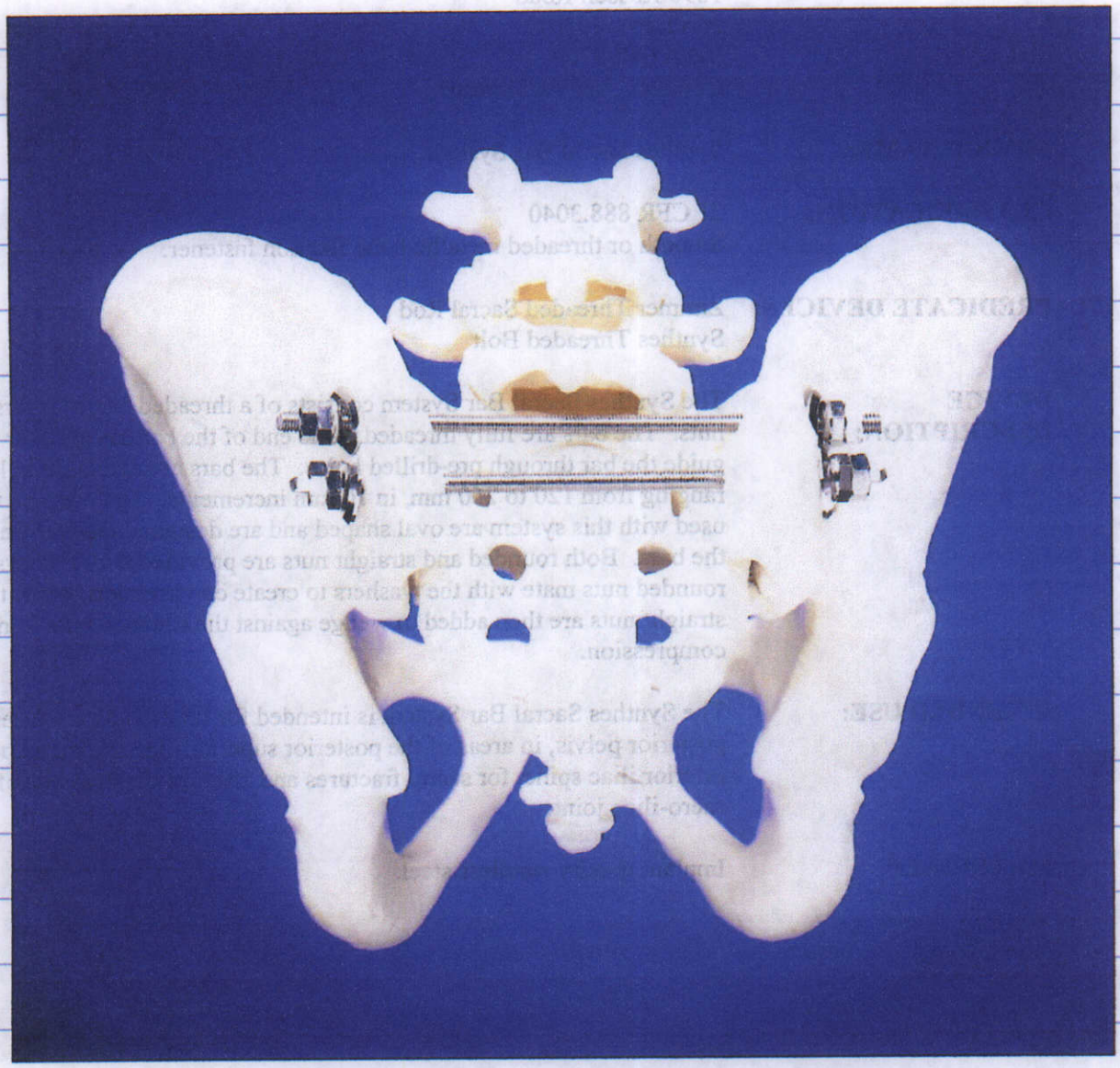
Sacral Bar Kit

TECHNIQUE GUIDE

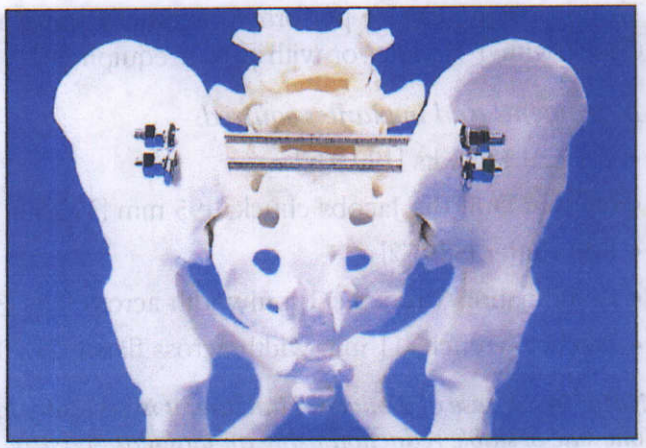


SYNTHES® *Original Instruments and Implants of the Association for the Study of Internal Fixation — AO ASIF*

Sacral Bar Kit

Indications

Synthes Sacral Bars are indicated for fixation of the posterior pelvis, in areas of the posterior superior iliac spine, posterior inferior iliac spine, for sacral fractures, and fracture dislocations of the sacroiliac joint.



Features

- Sacral washer prevents rounded sacral nut from pressing into cortical bone
- Trocar tip for easy passage through soft tissues
- Fully threaded, in lengths from 160 mm–260 mm, in 20 mm increments
- Kits available sterile and nonsterile

Technique

This procedure can be performed manually using a Universal Chuck with T-Handle, or with power equipment.

Instruments and implants required:

- 2 Sacral Bar Kits [199.93x]
- 6.0 mm Drill Bit, Jacobs chuck, 195 mm [310.60J] (included in kit)
- Rod Cutter [388.72]
- Combination Wrench, 11 mm width across flats [321.16] *or*
- Ratchet Wrench, 11 mm width across flats [321.20]

Note: *In the case of a bilateral fracture, it is necessary to have at least one side of stable reduction using an iliosacral screw or posterior plate in addition to inserting sacral bars.*

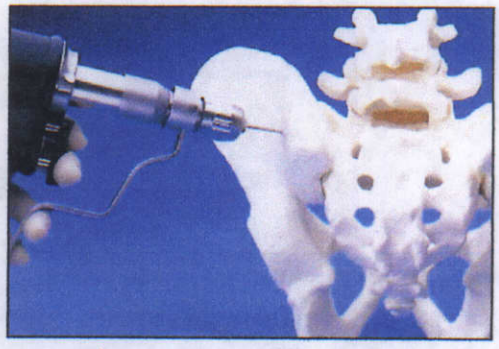
The correct length of the sacral bar should extend 25–30 mm on either side of the posterior iliac crests (bar will be cut to size intraoperatively).

1 Make incision

Make slightly curved bilateral incisions just lateral to the posterior superior sacroiliac joint. The incision on the fracture side should be large enough to allow for direct visualization and reduction.

2 Reduce and stabilize fracture

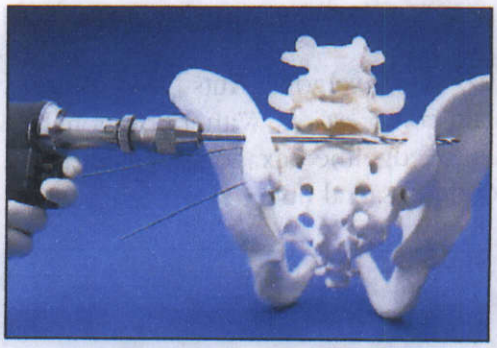
Reduce the fracture using pointed reduction clamps from the spinous process of the sacrum to the outer aspect of the posterior tubercle, or from the opposite side using pelvic reduction forceps. After reduction, two Kirschner wires should be placed across the sacroiliac joint for provisional stabilization.



Technique (continued)

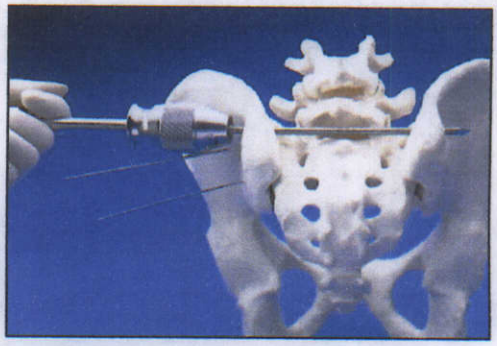
3 Drill

Drill a set of gliding holes using a 6.0 mm Drill Bit. The holes should be located so that the first bar is placed at the level of L5/S1 interspace as seen on C-arm or by palpation. The second set of holes should be at least 1.5 cm distal to the first. When drilling the gliding hole, make sure that the drill exits the inner aspect of the posterior tubercle above the sacral lamina. Care must be taken to ensure that there is enough bone in the posterior tubercle to hold the second bar. If not, use of an iliosacral screw or posterior plate will be necessary.



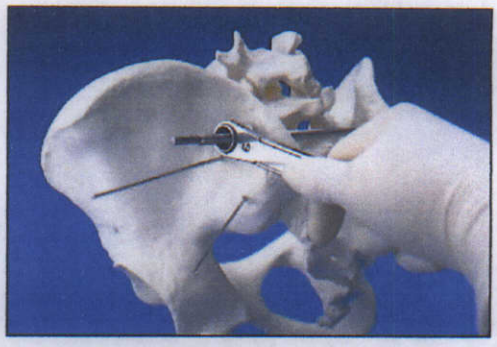
4 Insert 6.0 mm Threaded Sacral Bar

Drive the sharp trocar tip through the predrilled hole in the contralateral iliac spine. The sacral lamina must be seen, to ensure that the bar passes dorsal to it and does not enter the sacral canal; it may pass through the sacral spinous processes.



5 Apply sacral washers and sacral nuts

Place a 6.0 mm Sacral Washer [296.758] on each end of the sacral bar to prevent the sacral nuts from pressing into the bone. Mate the 6.0 mm Sacral Nuts, rounded [296.757] to the sacral washers. Tighten with an 11 mm wrench to obtain compression.



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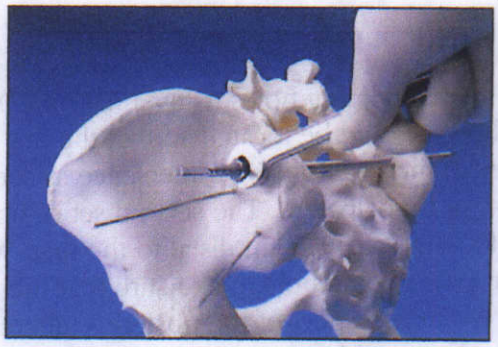
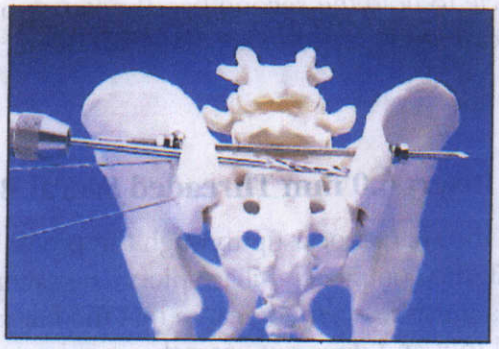
6 Apply hexagonal nuts

Add 6.0 mm Hexagonal Nuts [296.759] to maintain compression. With a hexagonal wrench, wedge the hexagonal nuts against the rounded sacral nuts.

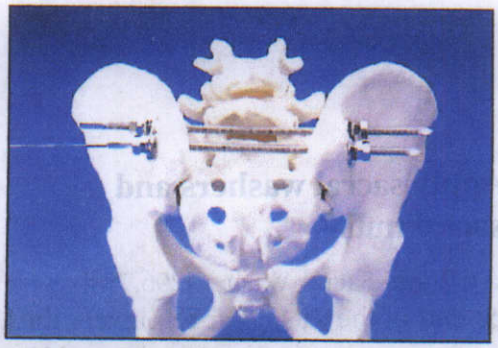


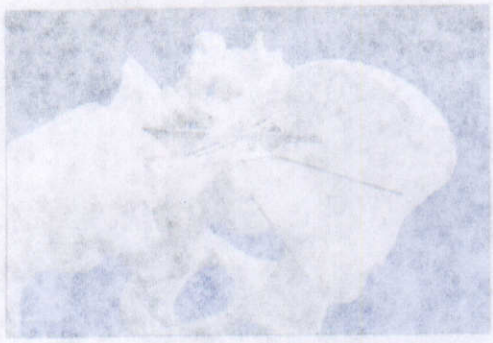
7 Place second bar

Repeat steps 4–6 for insertion of the second sacral bar. Two bars must be used to avoid rotation.



8 Remove Kirschner wires

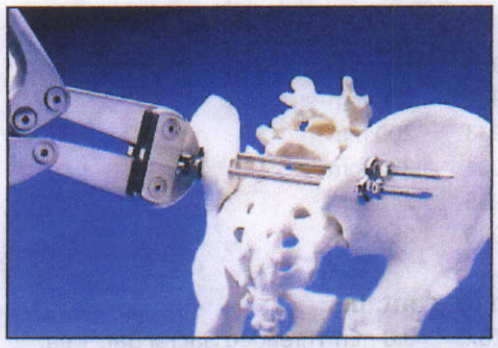


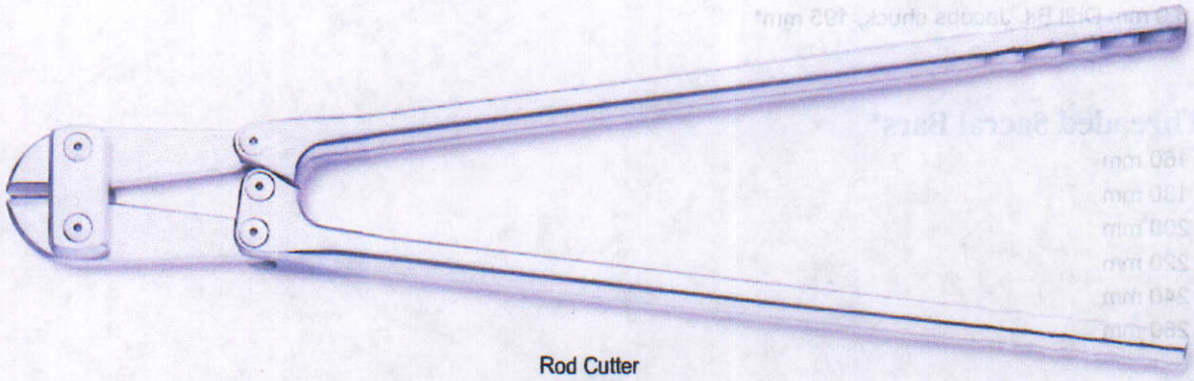


Technique (continued)

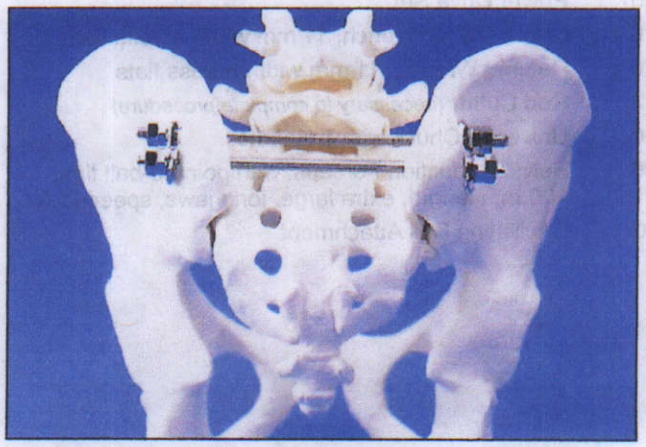
9 Trim Sacral Bars

Use the Rod Cutter [388.72] to cut the ends of the sacral bars flush with the hexagonal nuts.





Rod Cutter
[388.72]



Final construct

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Product Information

6.0 mm Threaded Sacral Bar Kits◊

199.931	160 mm
199.932	180 mm
199.933	200 mm
199.934	220 mm
199.935	240 mm
199.936	260 mm

Note:
Construct described in this Technique Guide requires two Sacral Bar Kits.

Each kit contains:

296.76x	6.0 mm Threaded Sacral Bar, 1 ea.
296.757	6.0 mm Sacral Nuts, rounded, 2 ea.*
296.758	6.0 mm Sacral Washers, 2 ea.*
296.759	6.0 mm Hexagonal Nuts, 2 ea.*
310.60J	6.0 mm Drill Bit, Jacobs chuck, 195 mm*

6.0 mm Threaded Sacral Bars*

296.761	160 mm
296.762	180 mm
296.763	200 mm
296.764	220 mm
296.765	240 mm
296.766	260 mm

Additionally Available

150.16	Compact Air Drive II Set *or*
105.957	Power Drive Set
321.16	Combination Wrench, 11 mm width across flats
321.20	Ratchet Wrench, 11 mm width across flats
388.72	Rod Cutter *(necessary to complete procedure)*
393.10	Universal Chuck with T-Handle
398.86	Pelvic Reduction Forceps, with pointed-ball tips, 400 mm length, extra large, long jaws, speed lock
511.20	Oscillating Drill Attachment

◊ *Kits available nonsterile or sterile-packed. Add "S" to catalog number to order sterile Sacral Bar Kit.*
* *Individual components may be purchased separately, nonsterile only.*

[redacted] [redacted]

MAR 2 0 2006

P.1/2

K060156

Section XII: 510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

NAME OF FIRM:
I.T.S. Implantat-Technologie-Systeme GmbH.
Autal 28.
Lassnitzhoehe A – 8301
AUSTRIA

510(k) FIRM CONTACT:
Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372

TRADE NAME: Straight Plate with Angular Stability & Screw System

COMMON NAME: Bone Plate & Screw System

CLASSIFICATION:
Plate, Fixation, Bone (see 21 CRF, Sec. 888.3030),
Screw, Fixation, Bone (see 21 CFR, Sec. 888.3040),
Washer, Bolt, Nut (see 21 CFR, Sec. 888.3030)

DEVICE PRODUCT CODE: HRS

SUBSEQUENT PRODUCT CODE: HWC, HTN

SUBSTANTIALLY EQUIVALENT DEVICES
I.T.S. GmbH Claviculaplate with Angular Stability (K050852)
Smith & Nephew Peri-Loc Locking Bone Plates and Locking Bone Screw System (K051735)
Zimmer Periarticular Locking Plates and Screws (K051098)
Synthes 4.5mm LCP Straight Reconstruction Plates (K051986)
Acumed Congruent Plate System (K012655)
I.T.S. GmbH FR.O.H. Calcaneus Repair System (K051642)
Synthes Sterile 3.5mm and 4.0mm Cannulated Screw (K963192)
Zimmer/Pioneer Cannulated Screw System (K003496)
Synthes (USA) Spherical Washers (K052483)

DEVICE DESCRIPTION:
The I.T.S. Straight Plate with Angular Stability is a low-profile 4, 6, or 8 hole plate with various length cortical and/or cancellous self-tapping stabilization locking and/or compression screws. The Straight Plate is made from CP titanium according to ASTM F 67-00 and all screws are made from 6-4 Alloyed Titanium according to ASTM F 136-02. The plate and screws are surface conditioned with a TIODIZE, Type II preparation.

The I.T.S. Screw System is a group of cannulated fracture fixation screws in various diameters of 4.0mm, 6.5mm, and 7.3mm and lengths. A complement of flat and spherical Washers are available with the system. All screws and washers are made from 6-4 Alloyed Titanium according to ASTM F 136-02 and are surface conditioned with a TIODIZE, Type II preparation.

[redacted] [redacted]

K060156

p 2/2

INTENDED USE:

The ***intended use*** of the I.T.S. Straight Plate with Angular Stability is to stabilize an osteotomy or fracture of small bones, long bones, the pelvis and the calcaneus in an adult or pediatric patient.

Indications for use include comminuted fractures, supercondylar fractures, intra-articular and extra-articular condylar fractures, fractures in osteopenic bone, nonunions, and malunions. And, as well, a fracture or osteotomy of the tibia, fibula, femoral condyle, acetabulum, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneal; hip arthrodesis, and provisional hole fixation. The 3.5mm Cortical and Cancellous Angle Stable Screws used in conjunction with the Straight Plate may be used only on small bones.

The ***intended use*** of the I.T.S. Screw System is for corrective osteotomy or internal fracture fixation of the patella, pelvis, ankle, and long bones in an adult or pediatric patient.

For the 4.0mm Cannulated Cancellous Screw, indications for use are for radial and ulnar fractures, fractures of the proximal/distal humerus and of the patella, and for tendon fixation, maisonneuve injuries and disruption of the syndesmosis with bimalleolar or supermalleolar fractures and the instability of the talus centering.
For the 6.5mm Cannulated Cancellous Screw, indications for use are for fractures of the femoral neck, tibiaplateau, of the sacrum and the articular cavity of the hip joint, and the metaphyseal fractures of the distal femur and distal tibia, fixation of the lleo-sacral joint, and fusion of the foot and ank
For the 7.3mm Cannulated Cancellous Screw, indications for use are for fractures of the calcaneus, femoral neck, tibiaplateau, and of the sacrum and the articular cavity of the hip joint, fusion of the foot and ankle, fixation of the lleo-sacral joint, and metaphyseal fractures of the distal femur and distal tibia.

The system(s) is not intended for spinal use.

BASIS OF SUBSTANTIAL EQIVLAENCE:

The I.T.S. Straight Plate with Angular Stability is substantially equivalent to the Smith & Nephew, Zimmer, Synthes, Acumed, and I.T.S. GmbH stabilizing bone plate systems. The I.T.S. Screw System is substantially equivalent to the I.T.S. GmbH, Zimmer, and Synthes cannulated screw and washer systems.

SUMMARY OF SAFETY AND EFFECTIVENESS:

The I.T.S. Straight Plate with Angular Stability and Screw System is shown to be safe and effective for use in fracture fixation of small and long bones in the body.

6.5 mm Cannulated Cancellous Screw

Thread 22 mm

Properties

- back-tapping flank
- 6.5 mm
- length from 25 to 120 mm in 5 mm steps
- 3.2 mm guide wire

Indications

- fractures of the femoral neck
- metaphysal fractures of the distal femur and distal tibia
- fractures of the tibial plateau
- fractures of the sacrum and the articular cavity of the hip joi
- fixation of the Ileo-sacral joint
- fusion of foot and ankle

6.5 mm Cannulated SCFE Screw

Transcutaneous Screwing of the Slipped Capital Femoral Epiphysis

Properties

- 10 mm thread
- 3.2 mm guide wire
- Back-tapping flank
- Large countersink head for easy removableness (trocar 7.5 mm / 30°)

Indications

- loosening of the epiphysis femoralis

GAUGE 2.
WITH CL

DEPT

7.3 mm Cannulated Cancellous Screw

fully threaded

Properties

- 7.3 mm
- length from 50 to 120 mm in 5 mm steps
- 3.2 mm guide wire

Indications

- fractures of the calcaneus
- fractures of the femoral neck

variable thread

Properties

- back-tapping flank
- 7.3 mm
- length from 40 to 120 mm in 5 mm steps
- 3.2 mm guide wire

Indications

- fractures of the femoral neck
- fractures of the tibial plateau
- fusion of foot and ankle
- fixation of Ileo-sacral joint
- fractures of the sacrum and the articular cavity of the hip joi
- metaphysal fractures of the distal femur and distal tibia

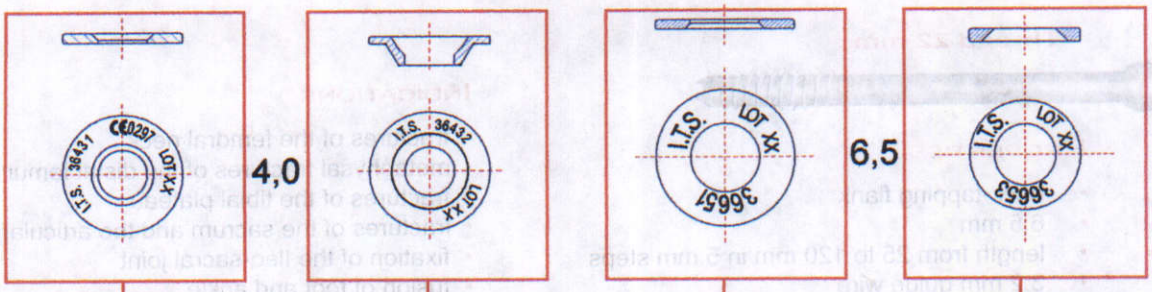
16 mm thread

Properties

- back-tapping flank
- 7.3 mm
- length from 80 to 120 mm in 5 mm steps
- 3.2 mm guide wire

Accessories

Flat Washer



36431 (flat)	
Ø internal	Ø external
4.5	11
for 4.0mm screws	

36432 (curved)	
Ø internal	Ø external
4.5	11
for 4.0mm screws	

36651 (flat)	
Ø internal	Ø external
7	14
for 6.5mm screws	

36653 (flat)	
Ø internal	Ø external
7	12.6
for 6.5mm screws	

36652 (curved)	
Ø internal	Ø external
7	14
for 6.5mm screws	

36731 (flat)	
Ø internal	Ø external
7.5	15
for 7.3mm screws	

36732 (curved)	
Ø internal	Ø external
7.5	14
for 7.3mm screws	

Washers are adjusted to the screw head and improve the formfitting of the screw head on the bone.

Depth gauge

item no.

Depth gauge for calibrated guide wire ø 3.2 mm — 59322

Depth gauge for calibrated guide wire ø 1.6 mm — 59162

Depth gauge for plate systems — 59022

(b)(4)Product Specs

(b)(4)Product Specs

(b)(4)Product Specs

(b)(4)Product Specs

(b)(4)Product Specs

(b)(4)Product Specs

(b)(4)Sterilization Info

AAMI

Standards

and

Recommended

Practices

Volume 1.2:
Sterilization, Part 2—Hospital equipment and industrial process control

Documents developed under the auspices of the
AAMI Sterilization Standards Committee

by:
Biological Indicators Working Group
Dry Heat Sterilization Working Group
Ethylene Oxide Residuals Working Group
Hospital Ethylene Oxide Sterilizer Working Group
Hospital Steam Sterilizer Working Group
Industrial Ethylene Oxide Sterilization Working Group
Industrial Steam Sterilization Working Group
Microbiological Methods Working Group
Returned Devices Decontamination Working Group
Radiation Sterilization Working Group
Reusable Devices Resterilization Working Group

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Contents — Sterilization, Part 2

*This (alpha)numeric designation appears in the black tab on the side of each page of all documents.

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Annex B
Sterilization cycles available in health care facilities

This annex describes sterilization cycles that are currently available for use in health care facilities or that are expected to be available for hospital applications by the end of 1994. Not all of the processes listed are in wide use at the time of publication of this report, and not all of them are suitable for any given medical device. It is important for medical device manufacturers to consult with appropriate sterilizer manufacturers for further information on the characteristics of new processes and their suitability for particular devices. It should be noted that pressure parameters are not given here for the various processes, some of which operate under significant positive or negative pressure. The processes and cycle parameters are listed for information only, and their inclusion here does not imply endorsement by AAMI.

Steam sterilization

Due to increasing cost constraints and, especially, to concerns about occupational exposure to toxic residuals of some gaseous and liquid chemical sterilization processes, sterilization by saturated steam is the preferred reprocessing method in health care facilities. Metal surgical instruments and other heat-stable medical devices are commonly sterilized by this method. Typical parameters for the generic cycles available for use in health care facilities are as follows:

Gravity-displacement steam sterilization

Wrapped items:

Temperature: 270° F to 275° F (132° C to 135° C)
Exposure time: 10 to 15 minutes

Temperature: 250° F to 254° F (121° C to 123° C)
Exposure time: 15 to 30 minutes

Unwrapped items ("flash" sterilization):

Temperature: 270° F (132° C)
Exposure time: 3 minutes (metal instruments only)
10 minutes (mixed porous, nonporous items)

Prevacuum steam sterilization

Wrapped items:

Temperature: 270° F to 275° F (132° C to 135° C)
Exposure time: 3 to 4 minutes

Unwrapped items ("flash" sterilization):

Temperature: 270° F (132° C)
Exposure time: 3 minutes (metal instruments only)
4 minutes (mixed porous, nonporous items)

Steam-flush pressure-pulse steam sterilization

Wrapped items:

Temperature: 250° F to 254° F (121° C to 123° C)
Exposure time: 20 minutes

Unwrapped items:

Temperature: 270° F to 275° F (132° C to 135° C)
Exposure time: 3 to 4 minutes

Ethylene oxide sterilization

Ethylene oxide (EO) sterilization is commonly used to sterilize items that cannot withstand high temperatures, such as medical devices composed entirely or in part of plastic. Currently, health care facilities generally use either 100% ethylene oxide or a sterilant mixture consisting of 12% ethylene oxide and 88% chlorofluorocarbon-12 (CFC-12); CFC-12 is used as a diluent to reduce the flammability of ethylene oxide. Because of concerns about the harmful effects of CFCs on the ozone layer of the earth's atmosphere, alternative EO sterilant mixtures are under development and some have begun to be introduced in health care facilities. Such mixtures are not in wide use at present, but will become more prevalent in the future as regulatory constraints reduce the production and use of CFC-12. Typical sterilization cycle parameters for the commonly used 100% EO and 12/88 EO/CFC-12 methods are given below, along with the parameters for two of the newer mixtures:

100% EO

Concentration EO: 883 milligrams per liter (mg/L)
Temperature: 131° F (55° C) or 99° F (37° C)
Exposure time: 60 to 250 minutes (depending on temperature)
Humidity: 70% RH minimum

Concentration EO: 725 mg/L
Temperature: 131° F (55° C) or 99° F (37° C)
Exposure time: 60 to 180 minutes (depending on temperature)
Humidity: 70% RH minimum

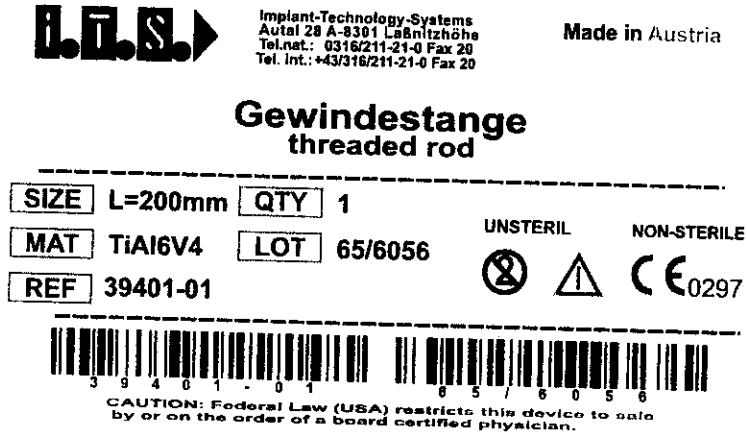
Section X: Labeling

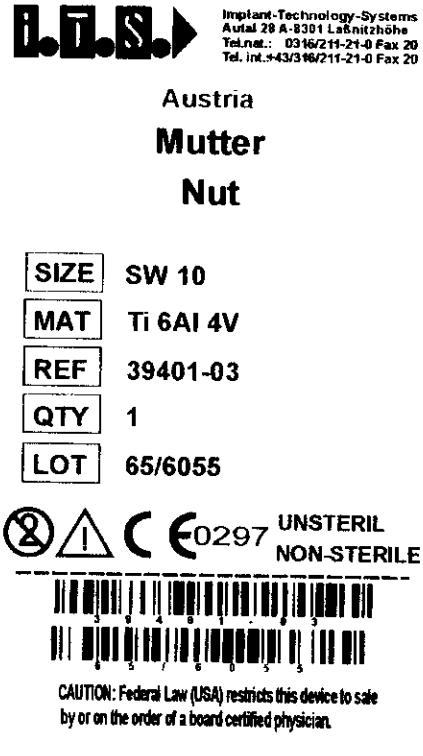
See attached sample labeling for various components of the I.T.S. Pelvic Reconstruction System (PRS) designating the manufacturer and address, product catalog number, product description, quantity in package, material, lot/production number traceability, and sterilization designation as **NONSTERILE.**

A package insert for the I.T.S. Pelvic Reconstruction System (PRS) is currently in development that will disclose the Indications, Warnings, Precautions, Contraindications, Sterilization as NONSTERILE as labled (with recommendations for in-hospital gravity autoclave per AAMI guidelines), and Materials. Also, the statement "Federal Law (USA) restricts this device to sale by or on order of a board certified physician" will be shown.

see Section II RPJ 12/22/2006

Sample Labeling for the I.T.S. PRS Sacral Rod





Sample Labeling for the I.T.S. PRS 7.3mm Cannulated SIJ Traction Screw & Washers

Implant-Technology-Systems
Autal 28 A-8301 Laßnitzhohe
Tel.nat.: 0316/211-21-0 Fax 20
Tel. int.+43/316/211-21-0 Fax 20

Made in Austria

7,3mm kanülierte
Spongiosaschraube,variables Gewinde
7,3mm Cannulated
cancellous screw, variable thread

SIZE	D=7,3mm; L=95mm
MAT	Ti 6Al 4V ELI
REF	31734-95
QTY	1
LOT	26/F14877

CE 0297 UNSTERIL NON-STERILE

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a board certified physician.

Implant-Technology-Systems
Autal 28 A-8301 Laßnitzhohe
Tel.nat.: 0316/211-21-0 Fax 20
Tel. int.+43/316/211-21-0 Fax 20

Made in Austria

Unterlegscheibe für
7,3mm Schraube, gewölbt
Cupped Washer for
7,3mm Screw

MAT	Ti 6Al4V
REF	36732
QTY	1
LOT	65/6015

UNSTERIL NON-STERILE CE 0297

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a board certified physician.

Implant-Technology-Systems
Autal 28 A-8301 Laßnitzhohe
Tel.nat.: 0316/211-21-0 Fax 20
Tel. int.+43/316/211-21-0 Fax 20

Made in Austria

Unterlegscheibe für
7,3mm Schraube, flach
Flat Washer for
7,3mm Screw

MAT	Ti 6Al4V
REF	36731
QTY	1
LOT	65/6017

UNSTERIL NON-STERILE CE 0297

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a board certified physician.

Sample Labeling for the I.T.S. PRS Multiple Type - Pelvic Plating System

Implant-Technology-Systems
Autal 28 A-8301 Laßnitzhöhe
Tel.nat.: 0316/211-21-0 Fax 20
Tel. int.+43/316/211-21-0 Fax 20

Austria

Gerade Beckenrekonstruktionsplatte

Straight pelvice reconstruction plate

SIZE	12 Loch; 12 holes
MAT	Titan; CP Titanium Grade 2 per ASTM F67-00
REF	21181-12
QTY	1
LOT	26/F14965

CE 0297 UNSTERIL NON-STERILE

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a board certified physician.

License DE 4343117, EP 1143 867, US 6322562

Implant-Technology-Systems
Autal 28 A-8301 Laßnitzhöhe
Tel.nat.: 0316/211-21-0 Fax 20
Tel. int.+43/316/211-21-0 Fax 20

Austria

Gebogene Beckenrekonstruktionsplatte

Pelvice reconstruction plate

SIZE	8 Loch; 8 holes / R108
MAT	Titan; CP Titanium Grade 2 per ASTM F67-00
REF	21195-8
QTY	1
LOT	26/F14981

CE 0297 UNSTERIL NON-STERILE

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a board certified physician.

License DE 4343117, EP 1143 867, US 6322562

Implant-Technology-Systems
Autal 28 A-8301 Laßnitzhöhe
Tel.nat.: 0316/211-21-0 Fax 20
Tel. int.+43/316/211-21-0 Fax 20

Austria

Gebogene Beckenrekonstruktionsplatte

Pelvice reconstruction plate

SIZE	8 Loch; 8 holes / R88
MAT	Titan; CP Titanium Grade 2 per ASTM F67-00
REF	21194-8
QTY	1
LOT	26/F14972

CE 0297 UNSTERIL NON-STERILE

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a board certified physician.

License DE 4343117, EP 1143 867, US 6322562

Implant-Technology-Systems
Autal 28 A-8301 Laßnitzhöhe
Tel.nat.: 0316/211-21-0 Fax 20
Tel. int.+43/316/211-21-0 Fax 20

Austria

Symphysenplatte

Symphysis plate

SIZE	4 Loch; 4 holes
MAT	Titan; CP Titanium Grade 2 per ASTM F67-00
REF	21161-4
QTY	1
LOT	65/6079

CE 0297 UNSTERIL NON-STERILE

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a board certified physician.

License DE 4343117, EP 1143 867, US 6322562

Implant-Technology-Systems
Autal 28 A-8301 Laßnitzhöhe
Tel.nat.: 0316/211-21-0 Fax 20
Tel. int.+43/316/211-21-0 Fax 20

Austria

Symphysenplatte

Symphysis plate

SIZE	6 Loch; 6 holes
MAT	Titan; CP Titanium Grade 2 per ASTM F67-00
REF	21161-6
QTY	1
LOT	65/6079

CE 0297 UNSTERIL NON-STERILE

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a board certified physician.

License DE 4343117, EP 1143 867, US 6322562

Sample Labeling for the I.T.S. PRS Multiple Type - Pelvic Plating System

Implant-Technology-Systems
Autal 28 A-8301 Laßnitzhöhe
Tel.nat.: 0316/211-21-0 Fax 20
Tel. int.+43/316/211-21-0 Fax 20

Austria

ISG Platte, geschlossen

SIJ-plate, closed

SIZE	4 Loch; 4 holes
MAT	Titan; CP Titanium Grade 2 per ASTM F67-00
REF	21173-4
QTY	1
LOT	26/F15056

0297 UNSTERIL
NON-STERILE

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a board certified physician.

License DE 4343117, EP 1143 867, US 6322562

Implant-Technology-Systems
Autal 28 A-8301 Laßnitzhöhe
Tel.nat.: 0316/211-21-0 Fax 20
Tel. int.+43/316/211-21-0 Fax 20

Austria

ISG Platte, L-Form, links

SIJ-plate, L-shape, left

SIZE	5 Loch; 5 holes
MAT	Titan; CP Titanium Grade 2 per ASTM F67-00
REF	21172-5
QTY	1
LOT	26/F15054

0297 UNSTERIL
NON-STERILE

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a board certified physician.

License DE 4343117, EP 1143 867, US 6322562

Implant-Technology-Systems
Autal 28 A-8301 Laßnitzhöhe
Tel.nat.: 0316/211-21-0 Fax 20
Tel. int.+43/316/211-21-0 Fax 20

Austria

4,5mm Kortikalisschraube

4,5mm Cortical Screw

SIZE	D=4,5mm; L=40mm
MAT	Ti 6Al 4V
REF	32455-40
QTY	1
LOT	26/F13834

0297 UNSTERIL
NON-STERILE

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a board certified physician.

Implant-Technology-Systems
Autal 28 A-8301 Laßnitzhöhe
Tel.nat.: 0316/211-21-0 Fax 20
Tel. int.+43/316/211-21-0 Fax 20

Austria

Spongiosaschraube für Beckenrekonstruktionsplatten

Anglestable cancellous screw for pelvice reconstruction plate

SIZE	D=5,9mm; L=40mm
MAT	Ti 6Al 4V ELI
REF	30591-40
QTY	1
LOT	26/F15309

0297 UNSTERIL
NON-STERILE

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a board certified physician.

License DE 4343117, EP 1143 867, US 6322562

Implant-Technology-Systems
Autal 28 A-8301 Laßnitzhöhe
Tel.nat.: 0316/211-21-0 Fax 20
Tel. int.+43/316/211-21-0 Fax 20

Austria

Spongiosa-Stabilisierungsschraube

Cancellous-stabilization screw

SIZE	D=5,9mm; L=40mm
MAT	Ti 6Al 4V ELI
REF	37592-40
QTY	1
LOT	26/F15322

0297 UNSTERIL
NON-STERILE

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a board certified physician.

License DE 4343117, EP 1143 867, US 6322562

I.T.S.

Autal 28, 8301 Lassnitzhöhe / Graz
AUSTRIA

I.T.S. Implant-Technology-Systems GmbH
Geschäftsführende Gesellschafterin: Dr. Eva Ruprechter

Tel ++43 (0)316 211 21 0
Fax ++43 (0)316 211 21 20
office@its-implant.com

Indications for Use

510(k) NUMBER: _____

DEVICE NAME: **PELVIC RECONSTRUCTION SYSTEM (PRS)**

The ***intended use*** of the I.T.S. Pelvic Reconstruction System (PRS) is to stabilize one or more pelvic bone fractures in the 'pelvic ring' area of the pelvis of an adult or pediatric patient which include the use of the following pelvic fracture fixation systems.

Indications for use of the I.T.S. PRS Low Profile - Multiple Type – Pelvic Plating System include:

1) Fracture reconstruction of the acetabulum, sacrum, illium, and entire pelvic ring,
2) Revision surgery of pseoduarthroses, non-unions and mal-unions,
3) Ilio-Iliac distance osteosynthesis,
4) Osteotomies,
5) Arthrodesis,
6) Sacroiliac joint dislocations, and
7) Symphysis pubis disruptures

Indications for use of the I.T.S. PRS Sacral Rod System include:

1) Fixation of fractures of the posterior pelvis,
2) Fixation of fractures of the posterior iliac spine,
3) Fixation of fractures of the posterior inferior iliac spine,
4) Dorsal stabilization of the posterior pelvic ring for unstable pelvic ring injuries,
5) Fixation of sacral fractures, and
6) Fracture dislocations of the sacro-iliac joint

Indications for use of the I.T.S. PRS 7.3mm Cannulated SIJ Traction Screw & Washer include fracture fixation of pelvic bone fractures where indicated and for periacetabular osteotomies.

The system(s) ~~is not intended for~~ spinal use, has not been studied in and is not intended for use in vertebral column fracture or fusion procedures.

RNT 12/22/2006

Prescription Use ___X___ AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Section XII: 510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

NAME OF FIRM: I.T.S. Implantat-Technologie-Systeme GmbH.
Autal 28.
Lassnitzhoehe A – 8301
AUSTRIA

510(k) FIRM CONTACT: Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372

TRADE NAME: Pelvic Reconstruction System (PRS)

COMMON NAME: Pelvic Bone Fixation Set

CLASSIFICATION: Plate, Fixation, Bone (see 21 CRF, Sec. 888.3030),
Pin, Fixation, Threaded (see 21 CRF, Sec. 888.3040)
Screw, Fixation, Bone (see 21 CFR, Sec. 888.3040),
Washer, Bolt, Nut (see 21 CFR, Sec. 888.3030)

DEVICE PRODUCT CODE: HRS

SUBSEQUENT PRODUCT CODE: JDW, HWC, HTN

SUBSTANTIALLY EQUIVALENT DEVICES
Synthes 3.5mm Low Profile Pelvic Reconstruction **(K031573)**
Stryker Trauma Pelvic Set **(K001614)**
Zimmer Pelvic Reconstruction Set
Synthes Sacral Bar System **(K001720)**
I.T.S. GmbH FR.O.H. Calcaneus Repair System **(K051642)**
Synthes 3.9mm Pelvic Screw **(K013044)**
I.T.S. Straight Plate with Angular Stability & Screw System **(K060156)**

DEVICE DESCRIPTION: The I.T.S. Pelvic Reconstruction System (PRS) encompasses a number of fracture fixation subsystems (multiple pelvic plate designs, sacral threaded rod, and cannulated screw & washer) for facture fixation and reconstruction of pelvic ring fractures in the pelvis.

The I.T.S. PRS Low Profile – Multiple Type – Pelvic Plating System consists of the following plate types: 1) A Straight Plate at a 4.0mm thickness with 10 to 14 hole length sizes, 2) A Curved Plate with a 108mm radius at a 2.5mm thickness with 4 to 16 hole length sizes, 3) A Curved Plate with a 88mm radius at a 2.5mm thickness also with 4 to 16 hole length sizes, 4) A Symphysis Plate at a 4.0mm thickness in both a 4 & 6 hole size, 5) A SacroIlliac-Joint (SIJ) L-Shaped Plate at a 2.5mm thickness in a left and right 5 hole size, and 6) A SIJ Closed Plate at a 2.5mm thickness in a 4 hole size.

All plate designs are low profile in thickness and made from CP Titanium. The PRS Pelvic Plating System also encompasses a number

of Cancellous (5.9mm std.compression & 5.9mm Locking screws) and Cortical (4.5mm std.compression screw) screw types and length sizes. All bone screws are pre-drilling and self-tapping in design and manufactured from high strength 6-4 Alloyed Titanium. All components (plates & screws) have a TIODIZE II surface treatment preparation.

The I.T.S. PRS *Sacral Rod System* consists of a threaded pin, wedge-shaped washers, and nut/locknut design with one end of the threaded pin having a trocar point. The assembled unit is used to stabilize ilio-iliac posterior pelvic ring disruption injuries. All components are manufactured from high strength 6-4 Alloyed Titanium material and have the TIODIZE II surface preparation.

The I.T.S. PRS *7.3mm Cannulated SIJ Traction Screw & Washer* is a pre-drilling, self-tapping, and back-tapping screw design for guided reduction of pelvic bone fractures. Washers (flat & curved) are available for use with the screw. All 7.3mm Cannulated Screws & washers are manufactured from high strength 6-4 Alloyed Titanium and have the TIODIZE II surface preparation.

INTENDED USE:

The ***intended use*** of the I.T.S. Pelvic Reconstruction System (PRS) is to stabilize one or more pelvic bone fractures in the pelvic ring area of the pelvis of an adult or pediatric patient which include the use of the following pelvic fracture fixation systems.

Indications for use of the I.T.S. PRS Low Profile - Multiple Type – Pelvic Plating System include:
1) Fracture reconstruction of the acetabulum, sacrum, illium, and entire pelvic ring,
2) Revision surgery of pseoduarthroses, non-unions and mal-unions,
3) Ilio-Iliac distance osteosynthesis,
4) Osteotomies,
5) Arthrodesis,
6) Sacroiliac joint dislocations, and
7) Symphysis pubis disruptures

Indications for use of the I.T.S. PRS Sacral Rod System include:
1) Fixation of fractures of the posterior pelvis,
2) Fixation of fractures of the posterior iliac spine,
3) Fixation of fractures of the posterior inferior iliac spine,
4) Dorsal stabilization of the posterior pelvic ring for unstable pelvic ring injuries,
5) Fixation of sacral fractures, and
6) Fracture dislocations of the sacro-iliac joint

Indications for use of the I.T.S. PRS 7.3mm Cannulated SIJ Traction Screw & Washer include fracture fixation of pelvic bone fractures where indicated and for periacetabular osteotomies.

The system(s) is not intended for spinal use. △ see Section II.

RAT 02/24/2006

BASIS OF SUBSTANTIAL EQIVLAENCE:

The I.T.S. Pelvic Reconstruction System (PRS) is substantially equivalent to the Synthes, Zimmer, and Stryker pelvic reconstruction systems and the I.T.S. GmbH stabilizing bone plating systems.

SUMMARY OF SAFETY AND EFFECTIVENESS:

The I.T.S. Pelvic Reconstruction System (PRS) is shown to be safe and effective for use in 'pelvic ring' bone fracture fixation of the pelvis.

(b)(4)Product Analysis Specs

JUN - 6 2003

K031573

3.0 510(k) Summary

Sponsor:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700
Contact:	Bonnie Smith
Device Name:	Synthes 3.5 mm Low Profile Pelvic Reconstruction Plate
Classification:	Class II, § 888.3030 – Single/multiple component metallic bone fixation appliances and accessories
Predicate Device:	Synthes 3.5 mm LCP Reconstruction Plate
Device Description:	Synthes 3.5 mm Low Profile Pelvic Reconstruction Plates consist of curved plates and straight plates that are contourable in three planes. The plates have a smooth, rounded profile. Plate holes are slightly oval, allowing 30 degrees of angulation in all directions. The 3.5 mm Low Profile Reconstruction Plate accepts Synthes 3.5 mm Cortex Screws and Synthes 3.5 mm Pelvic Screws.
Intended Use:	Synthes 3.5 Low Profile Pelvic Reconstruction Plate is intended for pelvic and acetabular reconstructive surgery and fracture fixation of the distal humerus, clavicle, and scapula.
Materials:	Stainless steel

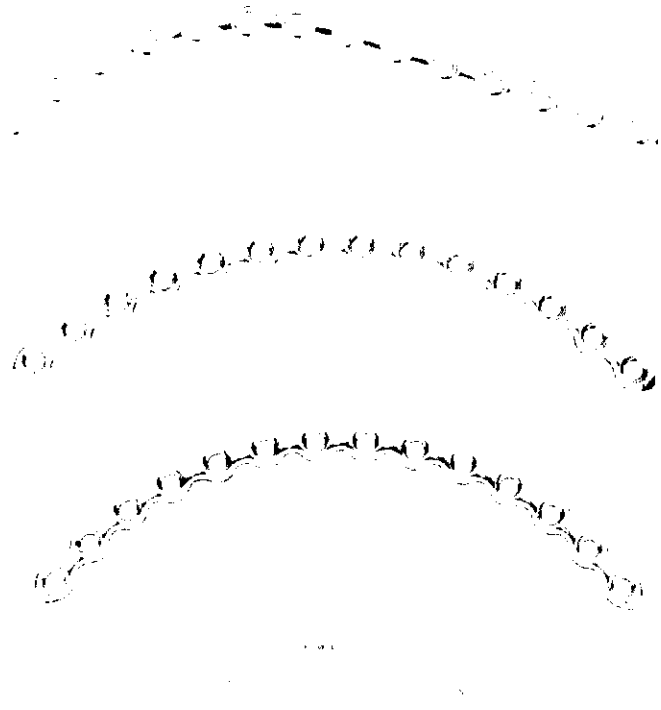
00005

3.5 mm Low Profile Pelvic System

The 3.5 mm Low Profile Pelvic System provides additional features and benefits to the pelvic and acetabular reconstructive surgeon.

Plate Features

- Low-profile plate improves contourability for easy intraoperative bending, when necessary
- Improved screw angulation
- Low-profile plate and edges to minimize soft tissue irritation
- Variety of precontoured shapes to minimize intraoperative contouring
- Compatible with both existing and new instruments and screws
- Implant quality 316L stainless steel
- Coaxial Combi holes in locking reconstruction straight and J-plates, and in Pubic Symphysis Plates, allow use of locking screws or cortex screws in the same round conical plate hole



3.5 mm Low Profile Pelvic System Instruments

- New instruments specifically designed to provide improved function with the 3.5 mm Low Profile Reconstruction Plates.

Indications

The Synthes 3.5 mm Low Profile Reconstruction Plate is intended for pelvic and acetabular reconstructive surgery and fracture fixation of the distal humerus, clavicle, and scapula.

- Designed for easy contouring
- Edge designed to minimize soft tissue irritation
- 316L stainless steel

3.5 mm Low Profile Reconstruction Plates (straight)

- 3–20 holes
- Improved screw angulation
- Available with or without coaxial Combi holes

3.5 mm Low Profile Curved Reconstruction Plates

- 88 mm or 108 mm radius of curvature
- 6–16 holes
- Improved screw angulation

3.5 mm Wide Angle Low Profile Reconstruction Plates (straight)

- Larger diameter hole in thicker plate allows maximum screw angulation
- 3–20 holes

3.5 mm Low Profile Reconstruction J-Plates

- Precontoured to fit the pelvic brim
- 88 mm radius of curvature in curved portion of plate
- Left and right plates
- 10–16 holes
- Available with or without coaxial Combi holes

3.5 mm Pubic Symphysis Plates

- 4 and 6 coaxial Combi holes
- Precontoured to fit the pubic symphysis
- 60 mm radius of curvature
- 3 suture holes
- Cold-worked for improved strength

Screws

3.5 mm Cortex Screws and 3.5 mm Pelvic Cortex Screws

- Deep hexagonal recess minimizes stripping of the screwhead or driver
- 10 mm to 150 mm lengths

[illegible] Low Profile Pelvic System implant and instrument configurations may be customized. The customer can choose from the following trays to combine.

[illegible] can be combined with any one of the graphic cases or graphic case lids listed below.

[illegible]	Single Level Graphic Case Base, 510 mm x 250 mm
[illegible]	Two Level Graphic Case Base, 510 mm x 250 mm
[illegible]	Three Level Graphic Case Base, 510 mm x 250 mm
690.422	Lid for 3.5 mm Low Profile Pelvic Retractors
690.426	Lid for 3.5 mm Low Profile Pelvic System Implant Set
690.427	Lid for 3.5 mm Low Profile Pelvic System Instruments
690.428	Lid for 3.5 mm Low Profile Pelvic System Reduction Instruments
690.429	Lid for 3.5 mm Low Profile Pelvic System
690.421	Lower Tray for 3.5 mm Low Profile Pelvic Retractors
690.423	Tray for 3.5 mm Low Profile Reconstruction J-Plates
690.424	Tray for 3.5 mm Low Profile Wide Angle Reconstruction Plates
690.431	Tray for 3.5 mm Low Profile Pelvic System Instruments
690.432	Upper Tray for 3.5 mm Low Profile Pelvic Retractors
690.433	Lower Tray for 3.5 mm Low Profile Pelvic System Reduction Instruments
690.434	Upper Tray for 3.5 mm Low Profile Pelvic System Reduction Instruments
690.435	Tray for 3.5 mm Locking Low Profile Reconstruction Plates
690.436	Tray for 3.5 mm Low Profile Reconstruction Plates
690.437	Tray for 3.5 mm Low Profile Pelvic System Cortex Screws
690.438	Screw Rack for 3.5 mm Low Profile Locking Screws
690.439	Tray for 3.5 mm Low Profile Pelvic System StarDrive Cortex Screws
690.816	Full Tray for 510 mm x 250 mm graphic case
690.817	Full Tray Finger Mat for 510 mm x 250 mm graphic case

[illegible] Implant Sets (including cases and lids)

01.100.00[illegible]	3.5 mm Low Profile Pelvic System Implant Set
01.100.00[illegible]	3.5 mm Low Profile Pelvic System Reduction Instrument Set
01.100.00[illegible]	3.5 mm Low Profile Pelvic System Retractor Set
01.100.01[illegible]	3.5 mm Low Profile Pelvic System Instrument Set

[illegible] Trays

01.100.01[illegible]	3.5 mm Low Profile Pelvic Reconstruction Plate Tray
01.100.02[illegible]	3.5 mm Wide Angle Low Profile Reconstruction Plate Tray
01.100.03[illegible]	3.5 mm Low Profile Reconstruction J-Plate Tray
01.100.042	3.5 mm Locking Low Profile Reconstruction Plate Tray
01.100.112	3.5 mm Low Profile Pelvic System Screw Tray with Locking Screws
01.100.122	3.5 mm Low Profile Pelvic System Screw Rack for Locking Screws
01.100.132	3.5 mm Low Profile Pelvic System StarDrive Screw Tray without Locking Screws
01.100.142	3.5 mm Low Profile Pelvic System Screw Tray without Locking Screws

Instruments

03.100.011	Spoon Retractor, medium, 268 mm
03.100.012	Spoon Retractor, large, 323 mm
03.100.013	Sciatic Nerve Retractor
03.100.014	Sciatic Nerve Retractor, long
03.100.015	Malleable Retractor, 20 mm width
03.100.016	Malleable Retractor, 30 mm width
03.100.017	Malleable Retractor, 40 mm width
03.100.018	Straight Ball Spike, 6.5 mm ball diameter, 320 mm
03.100.019	Straight Ball Spike, long, 6.5 mm ball diameter, 420 mm
03.100.020	Straight Reduction Forceps, with pointed ball tips, 6.5 mm ball diameter, 257 mm
03.100.021	Angled Reduction Forceps, small, with pointed ball tips, 6.5 mm ball diameter, 195 mm
03.100.022	Angled Reduction Forceps, large, with pointed ball tips, 6.5 mm ball diameter, 240 mm
03.100.023	Reduction Forceps, with pointed ball tips, 6.5 mm ball diameter, 400 mm
03.100.024	Asymmetric Reduction Forceps, with pointed ball tips, 6.5 mm ball diameter, 404 mm
03.100.025	Low Profile Pelvic System Reduction Forceps, used with 3.5 mm screws, 250 mm
03.100.027	Round Disk, 6.5 mm hole diameter
03.100.028	Rectangular Disk, 6.5 mm hole diameter
03.100.029	Medium Bone Hook, long, 330 mm
03.100.030	Large Bone Hook, long, 330 mm
03.100.031	Bending Pliers, for 3.5 mm Low Profile Reconstruction Plates
03.100.032	Ratcheting Handle with quick coupling
03.100.033	3.5 mm Screwdriver Shaft, hexagonal, long
03.100.040	2.8 mm Threaded Drill Guide, short
03.100.045	3.5 mm StarDrive Screwdriver Shaft, T15, 250 mm long
	Bending Templates
03.100.034	for 3.5 mm Low Profile Reconstruction Plates, 20 holes
03.100.035	for 3.5 mm Low Profile Reconstruction J-Plates (88 mm radius), 16 holes
03.100.036	for 3.5 mm Low Profile Curved Reconstruction Plates, 88 mm radius, 16 holes
03.100.037	for 3.5 mm Low Profile Curved Reconstruction Plates, 108 mm radius, 16 holes

3.5 mm Low Profile

Nonlocking	
245.023	02.100
245.024	02.100
245.025	02.100
245.026	02.100
245.027	02.100
245.028	02.100
245.029	02.100.10
245.030	02.100.11
245.031	02.100.111
245.032	02.100.112	hole
245.033	02.100.113	hole
245.034	02.100.114	hole
245.035	02.100.115	hole
245.036	02.100.116	hole
245.038	02.100.118	18 hole
245.039	02.100.120	20 hole

3.5 mm Low
Curved Reco

88 mm Radius	108 mm Radius	oles	ngth
245.906	245.876	holes	mm
245.908	245.878	holes	mm
245.910	245.880	holes	mm
245.912	245.882	holes	mm
245.914	245.884	holes	mm
245.916	245.886	holes	mm

eft		
245.950		
245.952		
245.954		
245.956		

Screws

204.640–204.750	3.5 mm Pelvic C self-tapping, 40	crews 50 mm*
204.810–204.838	3.5 mm Cortex self-tapping, 10	mm**
219.98	Washer, 7.0 mm	

*5 mm increments
**2 mm increments

eft	gth	
02.100.3	100.3	holes
02.100.3	100.3	holes
02.100.3	100.3	holes
02.100.3	100.3	holes

	ole s	ngth
02.100.00	holes	mm
02.100.00	holes	mm

SYNTHES (USA)
1302 Wrights Lane East
West Chester, PA 19380
Telephone: (610) 719-5000
To order: (800) 523-0322
Fax: (610) 251-9056

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2 Meadowpi
Mi ssauga, Ont
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To (800)
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USA and SYNTH

SYNTHES®

SYNTHES (USA)
To Order: (800) 523-0322

SYNTHES (Canada) Ltd.
To Order: (800) 668-1119

Inventory Control Form
3.5 mm Low Profile Pelvic System

Patient Data – For Charge Use

Name: _____

Date: _____

Screws

3.5 mm Pelvic Cortex Screws, self-tapping

		LENGTH
☐	204.640	40 mm
☐	204.645	45 mm
☐	204.650	50 mm
☐	204.655	55 mm
☐	204.660	60 mm
☐	204.665	65 mm
☐	204.670	70 mm
☐	204.675	75 mm
☐	204.680	80 mm
☐	204.685	85 mm
☐	204.690	90 mm
☐	204.695	95 mm
☐	204.700	100 mm
☐	204.705	105 mm
☐	204.710	110 mm
☐	204.715	115 mm
☐	204.720	120 mm
☐	204.725	125 mm
☐	204.730	130 mm
☐	204.735	135 mm
☐	204.740	140 mm
☐	204.745	145 mm
☐	204.750	150 mm

3.5 mm Cortex Screws, self-tapping

		LENGTH
☐	204.810	10 mm
☐	204.812	12 mm
☐	204.814	14 mm
☐	204.816	16 mm
☐	204.818	18 mm
☐	204.820	20 mm
☐	204.822	22 mm
☐	204.824	24 mm
☐	204.826	26 mm
☐	204.828	28 mm
☐	204.830	30 mm
☐	204.832	32 mm
☐	204.834	34 mm
☐	204.836	36 mm
☐	204.838	38 mm

3.5 mm Locking Screws, self-tapping, with StarDrive recess

		LENGTH
☐	212.101	10 mm
☐	212.102	12 mm
☐	212.103	14 mm
☐	212.104	16 mm
☐	212.105	18 mm
☐	212.106	20 mm
☐	212.107	22 mm
☐	212.108	24 mm
☐	212.109	26 mm
☐	212.110	28 mm
☐	212.111	30 mm
☐	212.112	32 mm
☐	212.113	34 mm
☐	212.115	36 mm
☐	212.116	38 mm
☐	212.117	40 mm
☐	212.119	45 mm
☐	212.121	50 mm
☐	212.123	55 mm
☐	212.124	60 mm
☐	212.125	65 mm
☐	212.126	70 mm
☐	212.127	75 mm
☐	212.128	80 mm
☐	212.129	85 mm
☐	212.130	90 mm
☐	212.131	95 mm

3.5 mm Threaded Plug, StarDrive

(for protection of the 3.5 mm Threaded Plate holes during contouring)

☐ 02.200.003

3.5 mm Cortex Screws, self-tapping, with T-15 StarDrive recess

		LENGTH
☐	02.200.010	10 mm
☐	02.200.012	12 mm
☐	02.200.014	14 mm
☐	02.200.016	16 mm
☐	02.200.018	18 mm
☐	02.200.020	20 mm
☐	02.200.022	22 mm
☐	02.200.024	24 mm
☐	02.200.026	26 mm
☐	02.200.028	28 mm
☐	02.200.030	30 mm
☐	02.200.032	32 mm
☐	02.200.034	34 mm
☐	02.200.036	36 mm
☐	02.200.038	38 mm
☐	02.200.040	40 mm
☐	02.200.042	42 mm
☐	02.200.044	44 mm
☐	02.200.045	45 mm
☐	02.200.046	46 mm
☐	02.200.048	48 mm
☐	02.200.050	50 mm
☐	02.200.055	55 mm
☐	02.200.060	60 mm
☐	02.200.065	65 mm
☐	02.200.070	70 mm
☐	02.200.075	75 mm
☐	02.200.080	80 mm
☐	02.200.085	85 mm
☐	02.200.090	90 mm
☐	02.200.095	95 mm
☐	02.200.100	100 mm
☐	02.200.105	105 mm
☐	02.200.110	110 mm
☐	02.200.115	115 mm
☐	02.200.120	120 mm
☐	02.200.125	125 mm
☐	02.200.130	130 mm
☐	02.200.135	135 mm
☐	02.200.140	140 mm
☐	02.200.145	145 mm
☐	02.200.150	150 mm

Plates

3.5 mm Low Profile Reconstruction Plates

	HOLES	LENGTH
245.023	3	39 mm
245.024	4	52 mm
245.025	5	65 mm
245.026	6	78 mm
245.027	7	91 mm
245.028	8	104 mm
245.029	9	117 mm
245.030	10	130 mm
245.031	11	143 mm
245.032	12	156 mm
245.033	13	169 mm
245.034	14	182 mm
245.035	15	195 mm
245.036	16	208 mm
245.038	18	234 mm
245.039	20	260 mm

3.5 mm Low Profile Curved Reconstruction Plates

88 mm radius	108 mm radius	HOLES	LENGTH
245.906	245.876	6	78 mm
245.908	245.878	8	104 mm
245.910	245.880	10	130 mm
245.912	245.882	12	156 mm
245.914	245.884	14	182 mm
245.916	245.886	16	208 mm

3.5 mm Wide Angle Low Profile Reconstruction Plates

	HOLES	LENGTH
02.100.203	3	39 mm
02.100.204	4	52 mm
02.100.205	5	65 mm
02.100.206	6	78 mm
02.100.207	7	91 mm
02.100.208	8	104 mm
02.100.209	9	117 mm
02.100.210	10	130 mm
02.100.211	11	143 mm
02.100.212	12	156 mm
02.100.213	13	169 mm
02.100.214	14	182 mm
02.100.215	15	195 mm
02.100.216	16	208 mm
02.100.218	18	234 mm
02 220	20	260 mm

3.5 mm Low Profile Reconstruction J-Plates (88 mm radius)

LEFT	RIGHT	HOLES	LENGTH
245.930	245.920	10	130 mm
245.932	245.922	12	156 mm
245.934	245.924	14	182 mm
245.936	245.926	16	208 mm

3.5 mm Locking Low Profile Reconstruction Plates

	HOLES	LENGTH
02.100.103	3	39 mm
02.100.104	4	52 mm
02.100.105	5	65 mm
02.100.106	6	78 mm
02.100.107	7	91 mm
02.100.108	8	104 mm
02.100.109	9	117 mm
02.100.110	10	130 mm
02.100.111	11	143 mm
02.100.112	12	156 mm
02.100.113	13	169 mm
02.100.114	14	182 mm
02.100.115	15	195 mm
02.100.116	16	208 mm
02.100.118	18	234 mm
02.100.120	20	260 mm

3.5 mm Locking Low Profile Reconstruction J-Plates (88 mm radius)

LEFT	RIGHT	HOLES	LENGTH
02.100.361	02.100.360	10	130 mm
02.100.363	02.100.362	12	156 mm
02.100.365	02.100.364	14	182 mm
02.100.367	02.100.366	16	208 mm

3.5 mm Locking Low Profile Pubic Symphysis Plate with Coaxial Combi Holes

	HOLES	LENGTH
02.100.004	4	57 mm
02.100.006	6	78 mm

Miscellaneous Implants

219.98	Washer, 7 mm
292.20	2.0 mm Kirschner Wire, 150 mm, 10 pack
294.68	6.0 mm Schanz Screw, spade point, 190 mm

Miscellaneous Instruments

Drill Bits, quick coupling

	DIAMETER	LENGTH
310.288	2.8 mm	165 mm
310.37	3.5 mm	195 mm
315.92	2.5 mm	230 mm, 200 mm calibration
324.210	2.5 mm	300 mm, 200 mm calibration
324.211	2.8 mm	300 mm, 200 mm calibration

Tap

311.31	for 3.5 mm Cortex Screws, 175 mm, 140 mm calibration

Bending Templates

03.100.034	for 3.5 mm, Low Profile Reconstruction Plates, 20 holes, 260 mm
03.100.035	for 3.5 mm, Low Profile Reconstruction J-Pates, 16 holes
03.100.036	for 3.5 mm, Low Profile Curved Reconstruction Plates, 88 mm radius, 16 holes
03.100.037	for 3.5 mm, Low Profile Curved Reconstruction Plates, 108 mm radius, 16 holes

AUG 4 2000

K001614

510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
Stryker Trauma Pelvic Set

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 201-825-4900
Contact Person:	Mary-Catherine Dillon Regulatory Affairs Team Member
Date Summary Prepared:	March 23, 2000

Device Identification

Proprietary Name:	Stryker Trauma Pelvic Set
Common Name:	Pelvic Set
Classification Name and Reference:	Plate, Fixation, Bone 21 CFR §888.3030

Predicate Device Identification

The Stryker Trauma Pelvic Set is substantially equivalent to the Synthes Pelvic Implant Set.

Device Description

The Stryker Trauma Pelvic Set consists of 88mm radius and 108mm radius curved plates, straight pelvic plates, straight acetabulum plates, and symphysis-pubis plates. All curves and straight plate components are available in 10.5mm widths and 2.5mm thicknesses. The symphysis-pubis plates are also available in a 12.5mm width and 3.2mm thickness. The subject components vary in length from 22.5mm to 474.5mm. The system also includes 3.5mm diameter and 4.5mm diameter screws. All devices in the system are provided both sterile and non-sterile.

Intended Use

The Stryker Trauma Pelvic Set is indicated for:

- Fractures of the acetabulum, sacrum, illium, and entire pelvic ring
- Revision surgery of pseoduarthroses, non-unions and mal-unions

- Osteonomies
- Arthrodeses
- Sacroilic joint dislocations
- Symphysis pubis disruptures

Materials

The subject components are manufactured from stainless steel which conforms to ASTM F-138.

Statement of Technological Comparison

The subject components of the Stryker Trauma Pelvic Set are substantially equivalent in design and intended use to the predicate device offered by Synthes.

Matta Pelvic Plating System

INDICATIONS | SYSTEM CONFIGURATION | SYSTE

Pelvic surgery represents one of the most technically demanding specialties within orthopaedic trauma. The Matta Pelvic Plating System offers the highly specialized surgeon a complete and specific system for addressing fractures of the pelvis and acetabulum.

Joel Matta, MD, world renowned as a premiere pelvic surgeon, is the designer of this system. The system features specific refinements including some of the familiar concepts he learned as a Letournel Fellow.

The system also offers a comprehensive, single set of instrumentation including reductions forceps, clamps and sciatic nerve retractors.

INDICATIONS

- Fractures of the:
  - Acetabulum
  - Sacrum
  - Illium
  - Pelvic Ring
- Revision Surgery of pseudoarthroses, non-unions and mal-unions
- Osteotomies
- Arthrodeses
- Sacroiliac Joint Dislocations
- Symphysis Pubis Disruptures

[Back to Top]

SYSTEM CONFIGURATION

- Material
  - Stainless Steel (Cold-Forged and Annealed)
  - Conforms to ISO/ASTM Standards: ISO 5832-1/ASTM F138
- Plating Options
  - Straight and curved plating options
  - Pre-curved Pelvic Plates (R108 and R88) to accommodate male and female anatomy
  - Low Screw Head Profile (Stainless Steel)
  - Fully Threaded, Self Tapping Cortical Screws;
    Diameter: 3.5mm and 4.5mm
  - Cancellous Screw;
    Diameter: 6.5mm; Lengths: 16mm and 32mm

[Back to Top]

SYSTEM HIGHLIGHTS

- Dedicated Symphysis Pubis Plate
- Annealed Acetabular Plate offers easier three dimensional bending
- Speciality Reduction Forceps and optimal Bone Clamp design offers improved visualization of the wound site
- Dedicated set of Instrumentation consists of Basic Instrument Tray; Reduction Instrument Tray; Implant Tray and Screw Rack

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Symphyis Pub

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zimmer

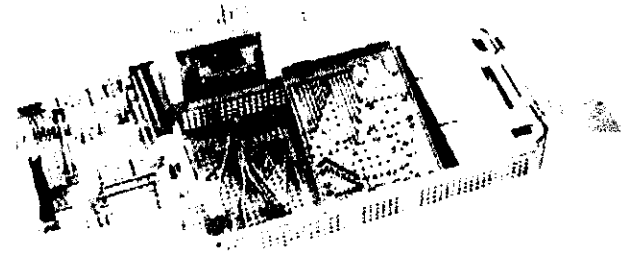
Zimmer® Plate and Screw System

A New Focus on Trauma Solutions

The Zimmer Plate and Screw System offers complete implant and instrument portfolios for mini, small basic fragment and pelvic reconstruction systems, in sterilization cases featuring unequaled convenience, storage and flexibility.

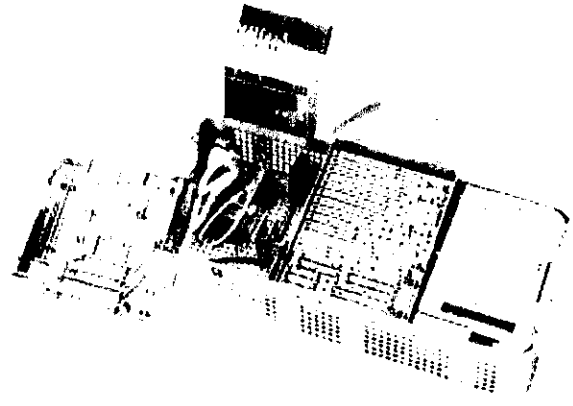
MINI FRAGMENT SET

- Plates and screws in 1.5mm, 2.0mm, and 2.7mm sizes
- Extensive screw line with hex and cruciform head options, and standard or self-tapping flute options
- Sterilization case stores optional implants, eliminating the need to sterilize individual products



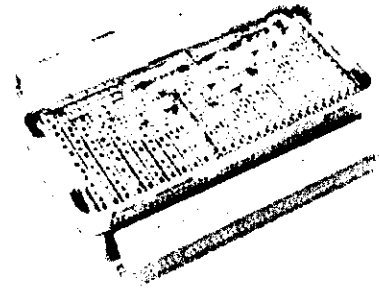
SMALL FRAGMENT SET

- Plates and screws in 3.5mm and 4.0mm sizes
- Full line of Compression Plates, 1/3 tubular plates, T plates, and Cloverleaf plates available
- Sterilization system combines flexibility and convenience with modular design and optional storage



BASIC FRAGMENT SET

- Plates and screws in 4.5mm and 6.5mm sizes; additional plate sizes, including 4.5mm reconstruction plates, can be stored in sterilization case base
- Sterilization container offers secure stacking to conserve table space



PELVIC RECONSTRUCTION SET

- Plates and screws in 3.5mm, 4.5mm, and 6.5mm sizes

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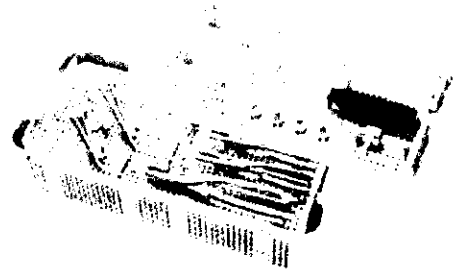
- Comprehensive scope of implants included in sterilization case improves hospital efficiency by reducing the need to open additional sets
- Provides complete line of Reduction Clamps for pelvic fracture manipulations



View Brochure

Please refer to the package inserts for complete product information, including contraindications, warnings, precautions, and adverse effects.

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Last updated 4/20/06

www.zimmer.com

↑ Zimmer Pelvic Set

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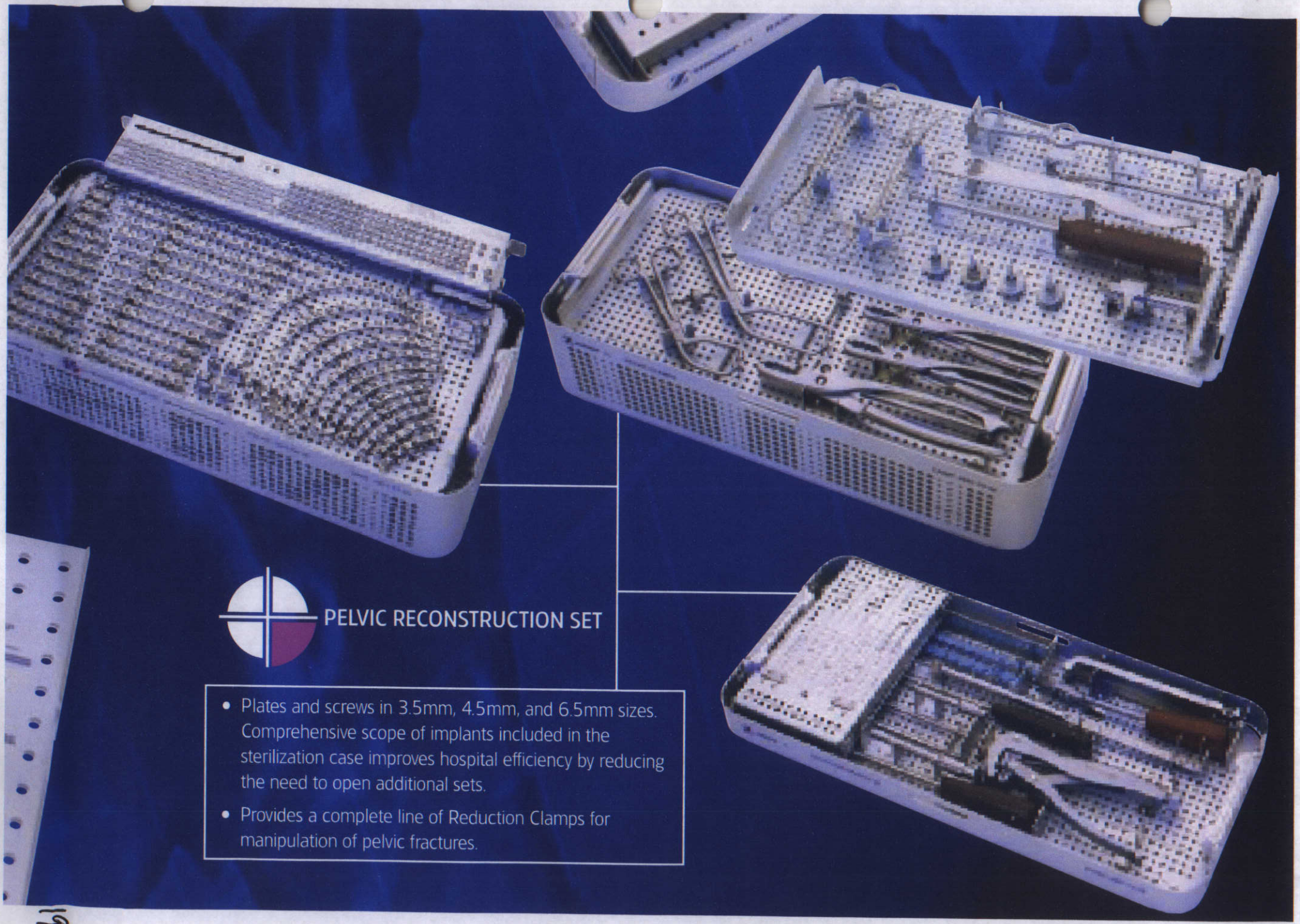


PELVIC RECONSTRUCTION SET

- Plates and screws in 3.5mm, 4.5mm, and 6.5mm sizes. Comprehensive scope of implants included in the sterilization case improves hospital efficiency by reducing the need to open additional sets.
- Provides a complete line of Reduction Clamps for manipulation of pelvic fractures.

K000120

SYNTHES®

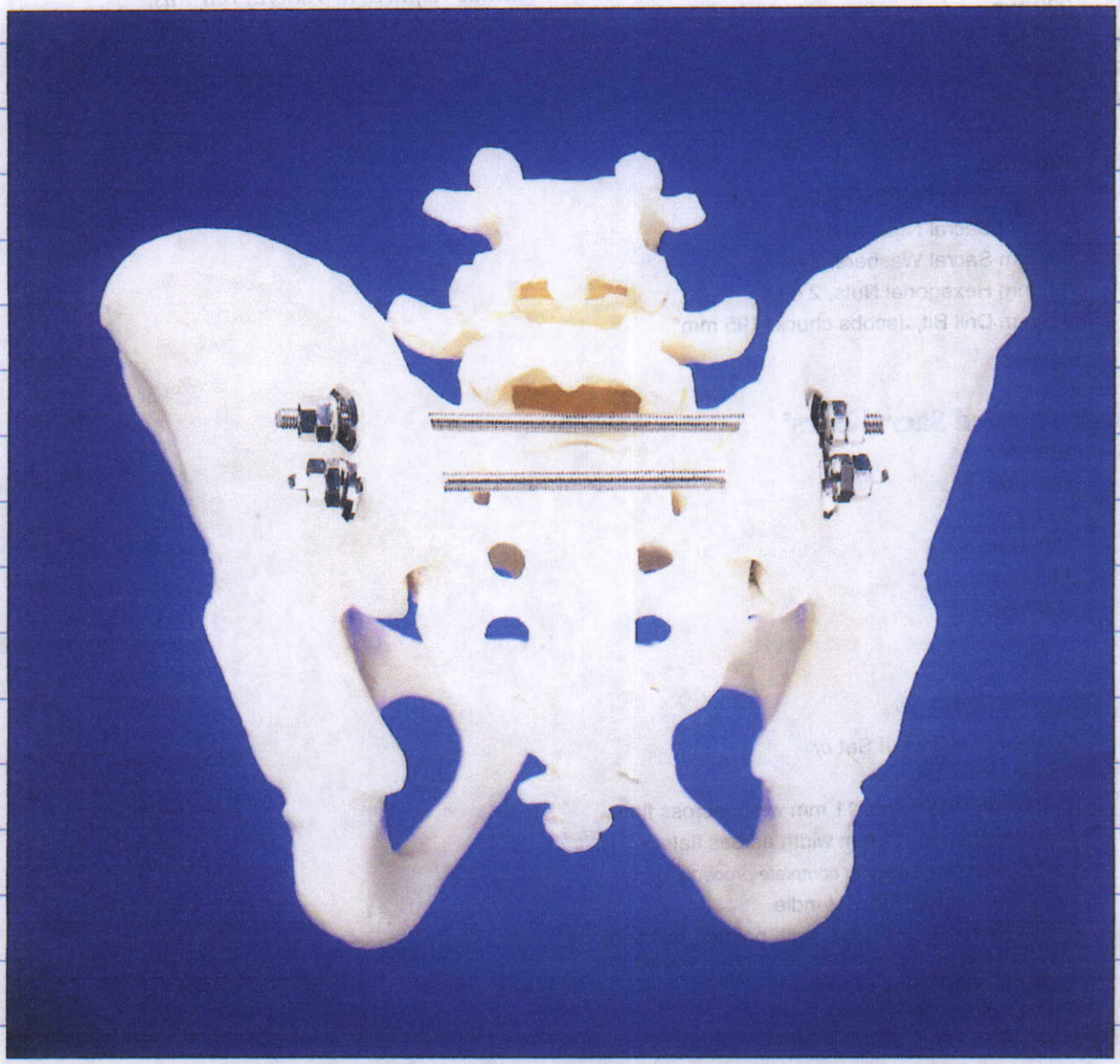
AUG 2 4 2000

3.0 Summary of Safety and Effectiveness Information

SPONSOR:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Angela Silvestri
DEVICE NAME:	Synthes Sacral Bar System
CLASSIFICATION:	21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener.
PREDICATE DEVICES:	Zimmer Threaded Sacral Rod Synthes Threaded Bolt
DEVICE DESCRIPTION:	The Synthes Sacral Bar System consists of a threaded bar, washers, and nuts. The bars are fully threaded. One end of the bar has a trocar point to guide the bar through pre-drilled holes. The bars are available in lengths ranging from 120 to 260 mm, in 10 mm increments. The washers that are used with this system are oval shaped and are designed to slide freely along the bars. Both rounded and straight nuts are provided with this system; the rounded nuts mate with the washers to create compression, while the straight nuts are then added to wedge against the rounded nuts to maintain compression.
INTENDED USE:	The Synthes Sacral Bar System is intended for fixation of fractures of the posterior pelvis, in areas of the posterior superior iliac spine and posterior inferior iliac spine, for sacral fractures and fracture-dislocations of the sacro-iliac joint.
MATERIAL:	Implant quality stainless steel.

Sacral Bar Kit

TECHNIQUE GUIDE



SYNTHES®

Original Instruments and Implants of the Association for the Study of Internal Fixation — AO ASIF

Product Information

6.0 mm Threaded Sacral Bar Kits◊

199.931	160 mm
199.932	180 mm
199.933	200 mm
199.934	220 mm
199.935	240 mm
199.936	260 mm

Note:
Construct described in this Technique Guide requires two Sacral Bar Kits.

Each kit contains:

296.76x	6.0 mm Threaded Sacral Bar, 1 ea.
296.757	6.0 mm Sacral Nuts, rounded, 2 ea.*
296.758	6.0 mm Sacral Washers, 2 ea.*
296.759	6.0 mm Hexagonal Nuts, 2 ea.*
310.60J	6.0 mm Drill Bit, Jacobs chuck, 195 mm*

6.0 mm Threaded Sacral Bars*

296.761	160 mm
296.762	180 mm
296.763	200 mm
296.764	220 mm
296.765	240 mm
296.766	260 mm

Additionally Available

150.16	Compact Air Drive II Set *or*
105.957	Power Drive Set
321.16	Combination Wrench, 11 mm width across flats
321.20	Ratchet Wrench, 11 mm width across flats
388.72	Rod Cutter *(necessary to complete procedure)*
393.10	Universal Chuck with T-Handle
398.86	Pelvic Reduction Forceps, with pointed-ball tips, 400 mm length, extra large, long jaws, speed lock
511.20	Oscillating Drill Attachment

◊ *Kits available nonsterile or sterile-packed. Add "S" to catalog number to order sterile Sacral Bar Kit.*

* *Individual components may be purchased separately, nonsterile only.*

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K051642

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510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990

510(k) Summary

NAME OF FIRM: I.T.S. Implantat-Technologie-Systeme GmbH.
Autal 28.
Lassnitzhoehe A - 8301
AUSTRIA

510(k) FIRM CONTACT: Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372

TRADE NAME: FR.O.H. Calcaneus Repair System

COMMON NAME: Bone Plate & Cannulated Cancellous Bone Screw System

CLASSIFICATION: Plate, Fixation, Bone (see 21 CRF, Sec. 888.3030)

Smooth or threaded metallic bone fixation fastener
(see 21 CFR, Sec. 888.3040)

DEVICE PRODUCT CODE: HRS & HWC

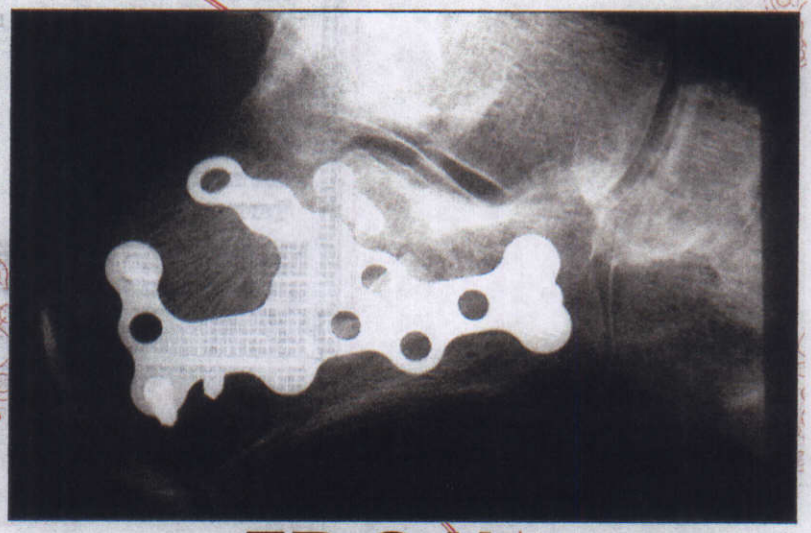
SUBSTANTIALLY EQUIVALENT DEVICES
Synthes Locking Calcaneal Plates **(K991407)**
DePuy/Ace Calcaneal Peri-articular Plate **(K993465)**
Ace/DePuy Cannulated Cancellous Bone Screw **(K903810)**

DEVICE DESCRIPTION: The I.T.S. FR.O.H. Calcaneus Repair System is a combination of fracture reduction and alignment instrumentation with either calcaneus plate and/or cannulated cancellous screw fixation across calcaneal heel bone fracture site(s). The 15-hole Calcaneus Plate (universal left and right in 2 sizes) is made from CP titanium according to ASTM F 67-00 and corresponding plate locking and self-tapping 3.5 & 4.2mm Cancellous Screws from 6-4 alloyed titanium according to ASTM F 136-02. The fully threaded 7.3mm Cannulated Cancelous Screw is in various lengths from 50 to 90mm in 5mm increment sizes and is also made from 6-4 alloyed titanium according to ASTM F 136-02. All titanium plates and screws are surface conditioned with a TIODIZE, Type II preparation.

510(k) Summary of Safety and Effectiveness Continued:

INTENDED USE:	The I.T.S. FR.O.H. Calcaneus Repair System is used to stabilize a inta-articular and/or extra-articular fracture(s) and/or osteotomy of the calcaneus heel bone in the foot.
BASIS OF SUBSTANTIAL EQIVLAENCE:	The I.T.S. FR.O.H. Calcaneus Repair System Calcaneal Plate is substantially equivalent to the Synthes **(K991407)** and, DePuy/Ace **(K993465)** plating systems. The I.T.S. FR.O.H. Calcaneus Repair System Cannulated Cancellous Screw is substantially equivalent to the DePuy/Ace **(K903810)** cannulated screw system.
SUMMARY OF SAFETY AND EFFECTIVENESS:	The I.T.S. FR.O.H. Calcaneus Repair System is shown to be safe and effective for use in fracture fixation of the calcaneus heel bone in the foot.

i.T.S. Implant-Technology-Systems



FR.O.H.

Calcaneus
Repair
Concept
according to
Univ.Prof Dr. **FR**öhlich,
Prim. Dr. **O**rtner,
Prim. Univ. Prof. Dr. **H**ertz

Distraction

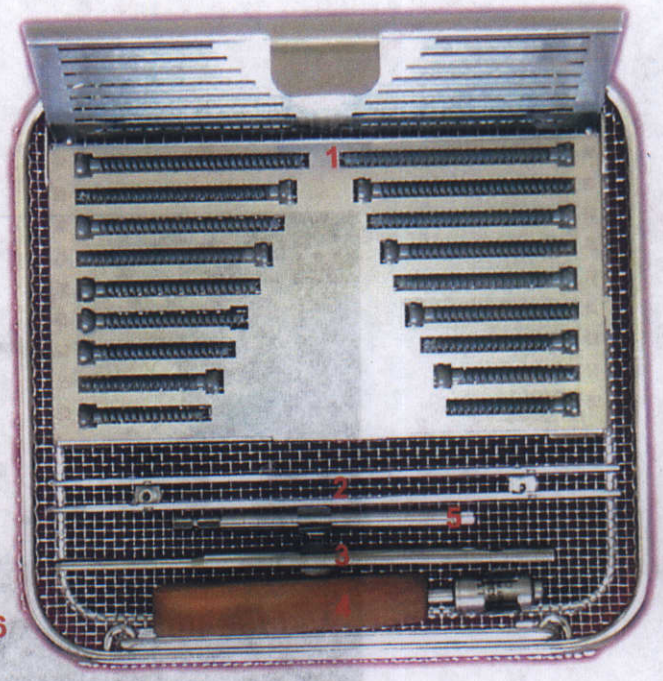
Fixation by angle stable plate

Screwing

7.3 mm CANNULATED CANCELLOUS SCREW, fully threaded for fractures of Calcaneus

PROPERTIES

- Diameter Outside 7.3 mm
- Length from 50 to 90 mm in 5 mm Steps
- 3.2 mm Guide Wire applicable
- Selfcutting and selfdrilling
- Material: Ti Al6 V4
- Surface Treatment



IMPLANTS

1	31731-xx	d=7.3 mm cannulated cancellous screw, fully threaded, Length=50-90mm, in 5mm Steps

INSTRUMENTS

2	35324-228	d=3.2mm calibrated Guide Wire, width thread, L= 228 mm
3	59321	Hook Depth Gauge for calibrated Guide Wire
4	53032	Handle, flat
5	54502-120	SW 5.0mm cannulated Screw Driver Shank, L=120mm
6	50172	Sterilization Case

CALCANEUS DISTRACTOR AND HEEL PRESS

INSTRUMENTS

210530001	Calcaneus Distractor, Fröhlich MD
210530011	Heel Press
35324-228	d=3.2mm Guide Wire, L= 228mm

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3. Summary of Safety and Effectiveness Information

Sponsor	Synthes (USA) 1690 Russell Road Paoli, PA 19301
Company Contact	Matthew M. Hull (610) 647-9700 ext. 7191
Name of the Device	Synthes 3.9 mm Pelvic Screw
Device Classification(s)	Class II, §888.3040 – Screw, Fixation, Bone
Substantial Equivalence	Documentation was provided which demonstrated the Synthes 3.9 mm Pelvic Screw to be substantially equivalent to other legally marketed devices.
Device Description	The Synthes 3.9 mm Pelvic Screw is a machined metallic screw with a hex drive head.
Indications	The 3.9mm pelvic screw is indicated for fracture fixation of the pelvis as well as for periacetabular osteotomies.
Materials	Stainless Steel

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K060156

Section XII: 510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

NAME OF FIRM:
I.T.S. Implantat-Technologie-Systeme GmbH.
Autal 28.
Lassnitzhoehe A – 8301
AUSTRIA

510(k) FIRM CONTACT:
Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372

TRADE NAME:
Straight Plate with Angular Stability & Screw System

COMMON NAME:
Bone Plate & Screw System

CLASSIFICATION:
Plate, Fixation, Bone (see 21 CRF, Sec. 888.3030),
Screw, Fixation, Bone (see 21 CFR, Sec. 888.3040),
Washer, Bolt, Nut (see 21 CFR, Sec. 888.3030)

DEVICE PRODUCT CODE: HRS

SUBSEQUENT PRODUCT CODE: HWC, HTN

SUBSTANTIALLY EQUIVALENT DEVICES
I.T.S. GmbH Claviculaplate with Angular Stability (K050852)
Smith & Nephew Peri-Loc Locking Bone Plates and Locking Bone Screw System (K051735)
Zimmer Periarticular Locking Plates and Screws (K051098)
Synthes 4.5mm LCP Straight Reconstruction Plates (K051986)
Acumed Congruent Plate System (K012655)
I.T.S. GmbH FR.O.H. Calcaneus Repair System (K051642)
Synthes Sterile 3.5mm and 4.0mm Cannulated Screw (K963192)
Zimmer/Pioneer Cannulated Screw System (K003496)
Synthes (USA) Spherical Washers (K052483)

DEVICE DESCRIPTION:
The I.T.S. Straight Plate with Angular Stability is a low-profile 4, 6, or 8 hole plate with various length cortical and/or cancellous self-tapping stabilization locking and/or compression screws. The Straight Plate is made from CP titanium according to ASTM F 67-00 and all screws are made from 6-4 Alloyed Titanium according to ASTM F 136-02. The plate and screws are surface conditioned with a TIODIZE, Type II preparation.

The I.T.S. Screw System is a group of cannulated fracture fixation screws in various diameters of 4.0mm, 6.5mm, and 7.3mm and lengths. A complement of flat and spherical Washers are available with the system. All screws and washers are made from 6-4 Alloyed Titanium according to ASTM F 136-02 and are surface conditioned with a TIODIZE, Type II preparation.

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INTENDED USE:

The ***intended use*** of the I.T.S. Straight Plate with Angular Stability is to stabilize an osteotomy or fracture of small bones, long bones, the pelvis and the calcaneus in an adult or pediatric patient.

Indications for use include comminuted fractures, supercondylar fractures, intra-articular and extra-articular condylar fractures, fractures in osteopenic bone, nonunions, and malunions. And, as well, a fracture or osteotomy of the tibia, fibula, femoral condyle, acetabulum, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneal; hip arthrodesis, and provisional hole fixation. The 3.5mm Cortical and Cancellous Angle Stable Screws used in conjunction with the Straight Plate may be used only on small bones.

The ***intended use*** of the I.T.S. Screw System is for corrective osteotomy or internal fracture fixation of the patella, pelvis, ankle, and long bones in an adult or pediatric patient.

For the 4.0mm Cannulated Cancellous Screw, indications for use are for radial and ulnar fractures, fractures of the proximal/distal humerus and of the patella, and for tendon fixation, maisonneuve injuries and disruption of the syndesmosis with bimalleolar or supermalleolar fractures and the instability of the talus centering.
For the 6.5mm Cannulated Cancellous Screw, indications for use are for fractures of the femoral neck, tibiaplateau, of the sacrum and the articular cavity of the hip joint, and the metaphyseal fractures of the distal femur and distal tibia, fixation of the Ileo-sacral joint, and fusion of the foot and ank
For the 7.3mm Cannulated Cancellous Screw, indications for use are for fractures of the calcaneus, femoral neck, tibiaplateau, and of the sacrum and the articular cavity of the hip joint, fusion of the foot and ankle, fixation of the Ileo-sacral joint, and metaphyseal fractures of the distal femur and distal tibia.

The system(s) is not intended for spinal use.

BASIS OF SUBSTANTIAL EQIVLAENCE:

The I.T.S. Straight Plate with Angular Stability is substantially equivalent to the Smith & Nephew, Zimmer, Synthes, Acumed, and I.T.S. GmbH stabilizing bone plate systems. The I.T.S. Screw System is substantially equivalent to the I.T.S. GmbH, Zimmer, and Synthes cannulated screw and washer systems.

SUMMARY OF SAFETY AND EFFECTIVENESS:

The I.T.S. Straight Plate with Angular Stability and Screw System is shown to be safe and effective for use in fracture fixation of small and long bones in the body.

ø 7.3 mm Cannulated Cancellous- Tension Screw
with variable thread lenght

Properties

- Back-tapping flank
- ø 7.3 mm
- Length from 40 to 120 mm in 5 mm steps
- ø 3.2 mm guide wire
- Self-drilling & self-tapping
- Material: Ti 6Al 4V ELI
- I.T.S. surface treatment

Length (mm)	Item No.
Screw	
40	31734-40
50	31734-50
55	31734-55
60	31734-60
65	31734-65
70	31734-70
75	31734-75
80	31734-80
85	31734-85
90	31734-90
95	31734-95
100	31734-100
105	31734-105
110	31734-110
115	31734-115
120	31734-120

ø 7.3 mm Cannulated Cancellous- Tension Screw
with end to end thread

Indications

- Fractures of the calcaneus
- Fractures of the femoral neck

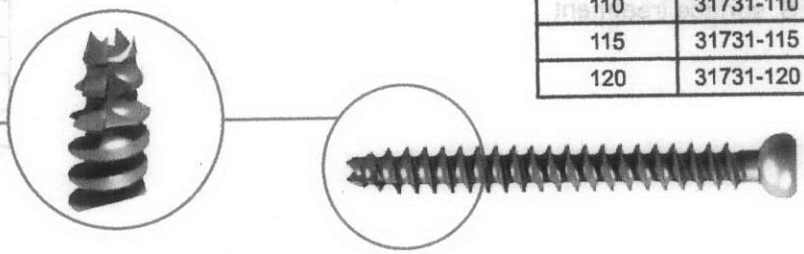
On request also lenght from 120 mm in 5 mm steps available.

end-to-end thread

Length (mm)	Item No.
Screw	
50	31731-50
55	31731-55
60	31731-60
65	31731-65
70	31731-70
75	31731-75
80	31731-80
85	31731-85
90	31731-90
95	31731-95
100	31731-100
105	31731-105
110	31731-110
115	31731-115
120	31731-120

Properties

- Back-tapping flank
- ø 7.3 mm
- length from 50 to 90 mm in 5 mm steps
- ø 3.2 mm guide wire
- Self-drilling & self-tapping
- Material: Ti 6Al 4V ELI
- I.T.S. surface treatment



Instrumente

35324-228	ø 3.2 mm calibrated guide wire, with thread, l= 228 mm
59321	Depth gauge for calibrated guide wire
53032	Hand grip, flat
54502-120	SW ø 5.0 mm cannulated allen insert, l=120 mm

ø 7.3 mm Cannulated Cancellous- Tension Screw
with 16 mm thread lenght

Properties

- Back-tapping flank
- ø 7.3 mm
- Length from 80 to 120 mm in 5 mm steps
- ø 3.2 mm guide wire
- Self-drilling & self-tapping
- Material: Ti 6Al 4V ELI
- I.T.S. surface treatment

Indications

- Fractures of the femoral neck
- Fractures of the tibiaplateau
- Fusion of foot and ankle
- Fixation of Ileo-sacral joint
- Fractures of the sacrum and the articular cavity of the hip joint
- Metaphysal fractures of the distal femur and distal tibia

Length (mm)	Item No.
Screw	
80	31732-80
85	31732-85
90	31732-90
95	31732-95
100	31732-100
105	31732-105
110	31732-110
115	31732-115
120	31732-120

6.5 mm Cannulated Cancellous Screw

Thread 22 mm

PROPERTIES

- back-tapping flank
- 6.5 mm
- length from 25 to 120 mm in 5 mm steps
- 3.2 mm guide wire

INDICATIONS

- fractures of the femoral neck
- metaphysal fractures of the distal femur and distal tibia
- fractures of the tibial plateau
- fractures of the sacrum and the articular cavity of the hip joint
- fixation of the Ileo-sacral joint
- fusion of foot and ankle

6.5 mm Cannulated SCFE Screw

Transcutaneous Screwing of the Slipped Capital Femoral Epiphysis

PROPERTIES

- 10 mm thread
- 3.2 mm guide wire
- Back-tapping flank
- Large countersink head for easy removableness (trocar 7.5 mm / 30°)

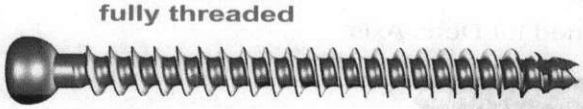
INDICATIONS

- loosening of the epiphysis femoralis

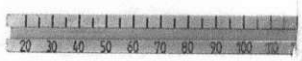
GAUGE 2.5
WITH CLAM

7.3 mm Cannulated Cancellous Screw

fully threaded



DEPTH



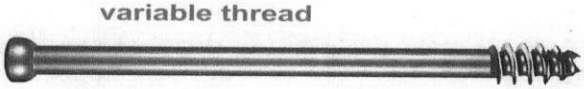
PROPERTIES

- 7.3 mm
- length from 50 to 120 mm in 5 mm steps
- 3.2 mm guide wire

INDICATIONS

- fractures of the calcaneus
- fractures of the femoral neck

variable thread



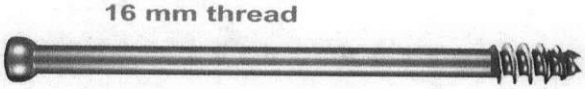
PROPERTIES

- back-tapping flank
- 7.3 mm
- length from 40 to 120 mm in 5 mm steps
- 3.2 mm guide wire

INDICATIONS

- fractures of the femoral neck
- fractures of the tibial plateau
- fusion of foot and ankle
- fixation of Ileo-sacral joint
- fractures of the sacrum and the articular cavity of the hip joint
- metaphysal fractures of the distal femur and distal tibia

16 mm thread



PROPERTIES

- back-tapping flank
- 7.3 mm
- length from 80 to 120 mm in 5 mm steps
- 3.2 mm guide wire

w system
n one source

4.0 mm Cannulated Cancellous Screw

fully threaded

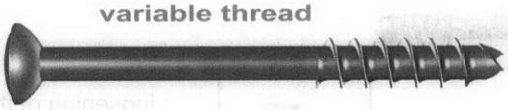
PROPERTIES

- 4.0 mm
- length from 45 to 60 mm in 5 mm steps
- 1.6 mm guide wire

INDICATIONS

- radial fractures
- ulnar fractures
- fractures of the proximal and distal humerus
- fractures of the patella
- tendon fixation

variable thread



PROPERTIES

- 4.0 mm
- length from 16 to 50 mm in 2 mm steps and 50 to 70 mm in 5 mm steps
- 1.6 mm guide wire

MM WRENCH
PING PIECE

9 mm thread

designed for Dens Axis

GAUGE

PROPERTIES

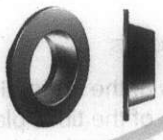
- 4.0 mm
- length from 16 to 50 mm in 2 mm steps and 50 to 70 mm in 5 mm steps
- 1.6 mm guide wire

INDICATIONS

- fractures of the Dens Axis

Washers

Washer curved



Washer flat

for 7.3 mm / 4.0 mm cancellous screw variable thread and 7.3 mm / 4.0 mm cancellous screw 16 mm / 9 mm thread

FEATURES

- selftapping and selfdrilling
- material: TiAL6V4 ELI
- I.T.S. surface treatment

ALBERT LIPPINCOTT

From: "CDRH OC RLMAIL" <RLMAIL@CDRH.FDA.GOV>
To: "'allippincott@msn.com'" <allippincott@msn.com>
Sent: Friday, July 21, 2006 12:53 PM
Subject: Annual Establishment Registration for 2007 for 3004369035

Dear Official Correspondent:

This letter confirms that the following establishment is now registered for the entire calendar year of 2007:

I.T.S. IMPLANTAT-TECHNOLOGIE-SYSTEME GMBH
AUTAL 28
LASSNITZHOEHE,
AUSTRIA A-8301

The establishment listed above is registered as a medical device establishment, performing the following operation(s):

MANUFACTURER

Please be aware that this confirmation does not indicate or imply approval of any product or activity at the establishment. It is also not a license or certification of any kind.

Please remember to report any changes to your establishment registration information using the form FDA 2891, Registration of Device Establishment, within the timeframes specified in Title 21 of the Code of Federal Regulations, Part 807.

If you have any questions regarding your registration or device listings, please send an email to reglist@cdrh.fda.gov or phone 240-276-0111.

Food and Drug Administration
Center for Devices and Radiological Health, HFZ-308
9200 Corporate Blvd.
Rockville, MD 20850-4015

212

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) N K MISHRA

Subject: 510(k) Number K063166

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: HRS/OR/II 21CFR§888.3040

Additional Product Code(s) with panel (optional): JDW/OR/II 21CFR§888.3040
HWC/OR/II 21CFR 888.3040

Review: Juanita (Branch Chief) OJDB (Branch Code) 12/20/06 (Date)

Final Review: [signature] (Division Director) 12/22/06 (Date)

Revised:4/2/03

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review? 2. Did we grant expedited review?		X
3. Have you verified that the Document is labeled Class III for GMP purposes? 4. If, not, has POS been notified?		X
5. Is the product a device? 6. Is the device exempt from 510(k) by regulation or policy? 7. Is the device subject to review by CDRH?	X X	X
8. Are you aware that this device has been the subject of a previous NSE decision? 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		X
10. Are you aware of the submitter being the subject of an integrity investigation? 11. If, yes, consult the ODE Integrity Officer. 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		X

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number K063166

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box):**

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☒ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	X	
Table of Contents.	X	
Truthful and Accurate Statement.	X	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	X	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	X	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	X	
Statement of Indications for Use that is on a separate page in the premarket submission.	X	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	X	
510(k) Summary or 510(k) Statement.	X	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	X	
Identification of legally marketed predicate device. *	X	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	X	
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.**]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:	X	
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

non-sterile
PDA Autoclaving
AAMI procedure

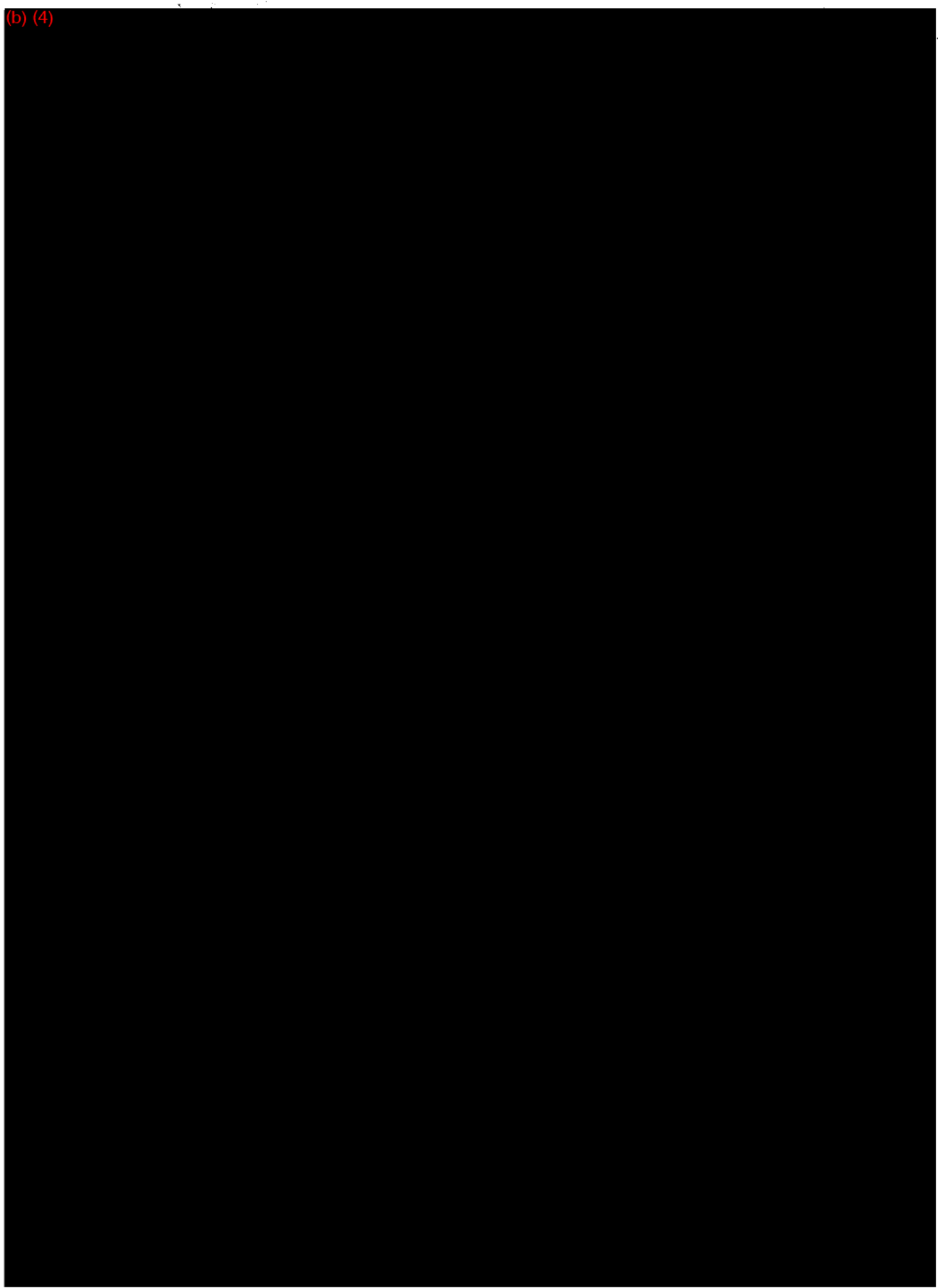
Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening X Yes ____ No

Reviewer: Lishu 12/15/06

Concurrence by Review Branch: Jonitu

Date: 12/20/06


(b) (4)

Section X: Labeling

See attached sample labeling for various components of the I.T.S. Pelvic Reconstruction System (PRS) designating the manufacturer and address, product catalog number, product description, quantity in package, material, lot/production number traceability, and sterilization designation as **NONSTERILE.**

A package insert for the I.T.S. Pelvic Reconstruction System (PRS) is currently in development that will disclose the Indications, Warnings, Precautions, Contraindications, Sterilization as NONSTERILE as labled (with recommendations for in-hospital gravity autoclave per AAMI guidelines), and Materials. A clause will be included stating: " The system(s) has not been studied in spinal use, and is not intended for use in vertebral column fracture or fusion procedures. Also, the statement "Federal Law (USA) restricts this device to sale by or on order of a board certified physician" will be shown.

12/12/06

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 063166

Reviewer: N. K. MISHRA

Division/Branch: DGRND

Device Name: ITS Pelvic Reconstruction SET

Product To Which Compared (510(K) Number If Known): K001270 K031573 K001614

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	X		If NO = Stop
3. Same Indication Statement?	X		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	X		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	X		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

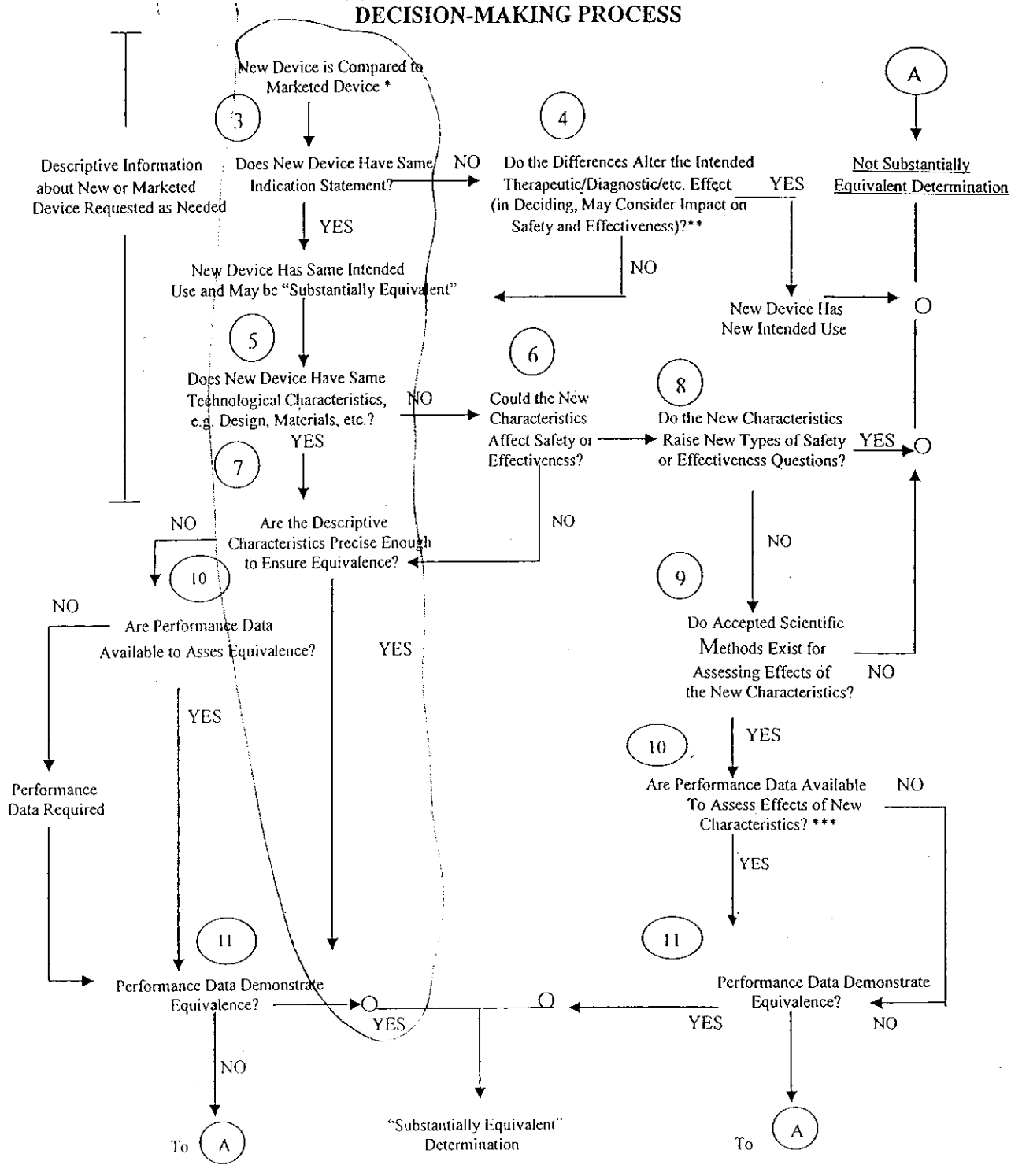
9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.