Manufactured by:
Southern Medical (Pty) Ltd
55 Regency Drive,
Route 21 Corporate Park,
Irene, Centurion, 0062, South Africa

P O Box 17198
Lyttleton, 0140
South Africa
Tel: +27 12 667 6243/4
Email: info@southmed.co.za

IMPORTANT: PLEASE READ
For detailed information on the Sterile Surgical Instrumentation, please consult the relevant device Surgical' Manual.

RADIOACTIVITY WARNING
No radioactive substance or radioactivity.

INTENDED USE:
Single use instrumentation provided sterile by Southern Medical is intended to be used for the implantation of orthopedic devices as described in the applicable Surgical Manual and Instructions for Use (IFU).

RECCOMENDED SURGICAL MATERIAL
Refer to the range specific surgical procedure provided by Southern Medical (Pty) Ltd.

INDICATIONS, CONTRAINDICATIONS, RISK & UNDESIRABLE EFFECTS
For indications, contraindications, risks and undesirable effects associated with single use instrumentation refer to the applicable Range specific Instructions for use (IFU).

USAGE WARNING:
Intended duration of use is less than 60 minutes.
Placement of this device is limited to qualified surgeons. Refer to surgical procedure and product brochure for more information.
Devices may not be implatnted.

WARNINGS & PRECAUTIONS: STERILITY, PACKAGING & RE-USE
The devices are sterilized via gamma irradiation and are provided **STERILE**. Do not re-sterilize the device. Re-sterilization could cause material degradation and could result in mechanical failure of the device, host rejection and/or post-operative infection.

Do not use implants if the packaging has been damaged or previously opened, or if the expiration date on the label has been exceeded.

The devices are **SINGLE-USE**. Do not re-use implants. An explanted implant must never be re-implanted. Re-use or re-implantation may result in cross-contamination or infection.

DISPOSAL
Single-use devices that have been in contact with blood or bodily fluids/tissues should be disposed of in accordance with the hospital's procedure for disposal of hazardous and/or biological waste. Users must wear surgical gloves and take care to avoid sharp edges. Devices that cannot be used because the packaging has been damaged but have not been in contact with blood or bodily fluids/tissues, should be returned to the manufacturer.

REPORTING
Any device-related adverse events must be reported to the manufacturer as soon as possible.

DESCRIPTIONS OF SYMBOLS USED IN PACKAGING

MANUFACTURER		USE BY	
CONSULT INSTRUCTIONS FOR USE		CATALOGUE NUMBER	REF
DO NOT RE-USE		CAUTION	
DO NOT RE-STERILIZE		LOT NUMBER	LOT
DATE OF MANUFACTURE		STERILIZED USING IRRADIATION	STERILE R
DO NOT USE IF PACKAGING IS DAMAGED			