Intramedullary nail and interlocking screw system

Country of origin | United States of America

Health problem addressed
According to WHO statistics, road traffic accidents (RTAs) cause about 25.4 million severe injuries per year. RTAs are projected to become the third leading cause of DALYs lost worldwide by 2020. Developing countries lack the surgical tools to treat severe fracture injuries effectively. Those who live in poverty cannot afford the cost of surgical implants they need in order to quickly recover and provide for their dependents.

Product description
The intermedullar (IM) nail and interlocking screw system is designed to be used without electricity or x-ray imaging in the operating room. The system consists of stainless steel nails which are placed down the middle of the bones with screws that are placed through the bone and nail to stabilize the fracture.

Product functionality
This method allows patients to walk using crutches the day after surgery and be discharged usually three days after surgery. The same instruments and implants of different sizes are used to treat fractures of the femur, tibia, and humerus. Results are recorded on an online database to ensure the proper technique is being followed and to learn more about fracture healing.

Developer's claims of product benefits
The IM nail and interlocking screw system's cost effectiveness is reflected in less disability after the fracture, ability to return sooner to work, and more efficient utilization of hospital beds. The IM nail interlocking screw technique is globally recognized as the preferred treatment for long bone fractures. This system makes it possible for surgeons to use this treatment on patients who couldn't afford it otherwise. Total cost is less than other systems of equivalent quality.

Operating steps
During surgery, the fracture is reduced and the stainless steel IM nail is placed through the canal of the bone. A target arm and special instruments are used to place screws through the slots in the nail and through the bone to stabilize the tibia, femur, or humerus fracture. No electricity or x-ray imaging is necessary for the surgery.

Development stage
FDA cleared for use in the USA. The stainless steel alloy composition is approved for implantation in humans. The associated online database has over 50,000 entries and is the largest database of treatment of long bone fractures in the world. This has been reviewed by surgeons and reported in peer reviewed medical journals. Biomechanical tests have been obtained as noted in listed articles.

Future work and challenges
Though the product is comparatively low-cost and available on a not-for-profit basis, it is a challenge to keep up with the increasing number of requests for the IM nail and interlocking screw system as financing is limited. Continual updating of technique is also a challenge due to the increasing number of hospitals which have this system.

User and environment
User: Physician, orthopaedic surgeon
Training: Yes; training and tools are given by surgeons familiar with the technique (over 10+ surgeries)
Maintenance: Yes; periodic replenishments (by nurse, technician, manufacturer, physician)

Environment of use
Settings: Rural, urban, secondary (general hospital), tertiary (specialists hospital)
Requirements: Operating room with sterile conditions, anesthesia personnel and machines, well trained nurses, and sterilizing personnel are all required

Product specifications
Dimensions (mm): 8-12 x 8-12 x 280-420
Weight (kg): 0.118-0.389
Consumables: Surgical supplies
Retail Price (USD): Varies
List price (USD): Varies
Other features: Portable
Year of commercialization: 2002
Currently sold in: United States, Vietnam, Iran, Guatemala, & Indonesia. Donated to 48 other countries

Contact details
Jeanne Dillner | Email jeanne.dillner@gmail.com | Telephone +1 509 371 1107 | Fax +1 509 371 1316
http://www.who.int/medical_devices
Disclaimer

Eligibility for inclusion in the compendium has been evaluated by EuroScan member agencies, WHO Collaborating Centres, and WHO. However, the evaluation by EuroScan member agencies, WHO Collaborating Centres, and WHO has been solely based on a limited assessment of data and information submitted in the developers’ applications and, where available, of additional sources of evidence, such as literature search results or other publicly available information. There has been no rigorous review for safety, efficacy, quality, applicability, nor cost acceptability of any of the technologies. Therefore, inclusion in the compendium does not constitute a warranty of the fitness of any technology for a particular purpose. Besides, the responsibility for the quality, safety and efficacy of each technology remains with the developer and/or manufacturer. The decision to include a particular technology in the compendium is subject to change on the basis of new information that may subsequently become available to WHO.

WHO will not be held to endorse nor to recommend any technology included in the compendium. Inclusion in the compendium solely aims at drawing stakeholders’ attention to innovative health technologies, either existing or under development, with a view to fostering the development and availability of, and/or access to, new and emerging technologies which are likely to be accessible, appropriate and affordable for use in low- and middle-income countries.

WHO does not furthermore warrant or represent that:

1. the list of innovative health technologies is exhaustive or error free; and/or that
2. the technologies which are included in the compendium will be embodied in future editions of the compendium; and/or that
3. the use of the technologies listed is, or will be, in accordance with the national laws and regulations of any country, including but not limited to patent laws; and/or that
4. any product that may be developed from the listed technologies will be successfully commercialized in target countries or that WHO will finance or otherwise support the development or commercialization of any such product.

WHO disclaims any and all liability and responsibility whatsoever for any injury, death, loss, damage, use of personal data, or other prejudice of any kind whatsoever that may arise as a result of, or in connection with, the procurement, distribution and/or use of any technology embodied in the compendium, or of any resulting product and any future development thereof.

Developers whose technology has been included in the compendium shall not, in any statement of an advertising, commercial and/or promotional nature, refer to their participation and/or inclusion in the compendium. In no case shall the latter use the WHO name and/or the emblem, or any abbreviation thereof, in relation to their business or otherwise.