

BLUE SHARK

BLUE SHARK 2006

Blue Shark is supplied in a single use kit with two sterile packs including the following:

	ITEM NUMBER
BLUE SHARK KIT Fixator and Instrumentation Pack	MMC-5000750ST

STERILE FIXATOR PACK	Q.TY
Anatomical stirrup, right	1
Anatomical stirrup, left	1
Ring, Large with clamp	1
Ring, Small with clamp	1

ACCESSORIES	ITEM NUMBER
Aluminum Ring	MMC-5000756
T-Wrench Ø12 for Aluminum Ring	MMC-5000121
Flat Wrench 12 mm	MMC-5000122

STERILE INSTRUMENTATION PACK	Q.TY
Flat Wrench - 15 mm	1
T Wrench - 15 mm	1
T Wrench for screws	1
Cannula guide	2
Trocar	1
K-Wire	2
Scissors	1
Scalpel	1
Cortical Self-drilling Screws, Ø 6x200	6

MATERIALS

Fixator Frame: Resistant polymeric composite

Screws: AISI 316LVM stainless steel; Conforms to ISO 5832-1 standards

Ring Accessories: Aluminum 7012 Alloy

PRODUCT IDENTIFICATION AND TRACEABILITY

All of Mikai's devices are identified by an item number and lot number and some also use a series number to assure traceability. This information is indicated on the packaging and devices.

MANUFACTURER'S INFORMATION

Blue Shark is manufactured by Mikai S.p.A.

Blue Shark is a registered trademark of Mikai S.p.A.

For the use of this device please consult the documentation provided by Mikai S.p.A.

Mikai S.p.A. conforms to ISO 13485 standards



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External fixator
for pelvic ring





The **Blue Shark** radiolucent pelvic fixator was designed by Mikai to resemble the anatomical structure of the pelvic ring using using CAD/CAM software to establish typical screw insertions. The conditions we sought to achieve in the development of this dedicated fixator were: quick, minimal instrumentation, radiolucent, compatible with MRI and CT, adaptable to different patient anatomies, and no interference with potential abdominal or urological surgeries. **Blue Shark** is practical for surgeons with a varied levels of experience thanks to the ease of use in implanting the fixator which allows for ~~even only~~ one person alone to rapidly stabilize a life threatening pelvic ring fracture. The radiolucent and MRI compatible qualities of the **Blue Shark** allow for a thorough diagnosis of concurrent abdominal, cranial or medullary injuries as well as cardiacprocedures or more complicated **orthopedic**

procedures such as a stabilization with percutaneous sacroiliac screws. The configuration of the fixator can even be modified at a later time for complete access of the abdominal and perineum areas; this allows for abdominal and urological surgical procedures while maintaining a rigid stabilization of the pelvic ring at all times.

INDICATIONS FOR USE

Blue Shark is indicated for use in emergency situations for patients that require a rapid stabilization of complex fractures of the pelvic ring associated with unstable blood circulation and which require essential diagnostic testing and/or abdominal or pelvic surgeries. **Blue Shark** can be utilized as a definitive remedy for type “B”fractures of AO classification (partially unstable fractures) and as a temporary remedy for type “C” fractures (generally unstable).



DESCRIPTION OF COMPONENTS



The sterile Blue Shark fixator kit is composed of:
Two expandable half rings. Each ring is made up of two semi-rings in the form of a musical tuning fork joined by a nut which expands to vary the angle during the pelvic reduction. A third ring is an accessory to the kit which allows for further variations of the fixator configuration.



Two stirrups (right and left) mirrored anatomical side rails follow the anatomical curve of the iliac crest and the superior ramus. Each stirrup has four clamps that move along the pertaining holes and three quick locks for the joining rings - these components are supplied pre-assembled on the stirrups.



Screws - Mikai's self-drilling self-tapping screws in a 6 mm diameter 200 mm length with a 40 mm thread. The clamp can be used as a guide for the screws that are usually two per side; these are implanted, based upon the surgeons discretion, according the antero-superior, antero-inferior or combined configuration (see surgical technique).



The instrumentation includes:

- Disposable scalpel (#11)
- Scissors
- K-wire Ø 2.0
- Two disposable wrenches to tighten the screws to the clamps and clamp the connecting rings in the desired position
- Disposable cannula to protect the interface between the skin and the screw during implant
- Disposable smooth tipped trocar

CLINICAL CASE STUDIES

CASE 1: 32 year old Male, motorcycle accident; type AO lesion B1.3

PREOP X-RAY

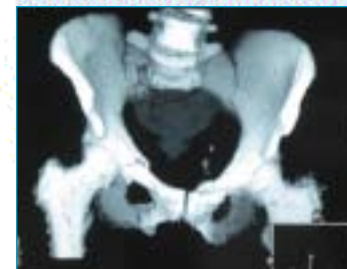


POSTOP X-RAY



CASE 2: 57 year old Female, fall injury; type AO lesion B2.

PREOP CT SCAN



POSTOP X-RAY

