BLUE SHARK

BLUE SHARK 2006

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

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

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

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

STERILE BLISTER 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: High resistant polymeric composite
Grasping Components: AISI 316LVM stainless steel; Conforms to ISO 5832-1 standards
Arc Accessories: Aluminum 7012 Alloy

PRODUCT IDENTIFICATION AND TRACEABILITY

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

MANUFACTURERS 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

CE 0476

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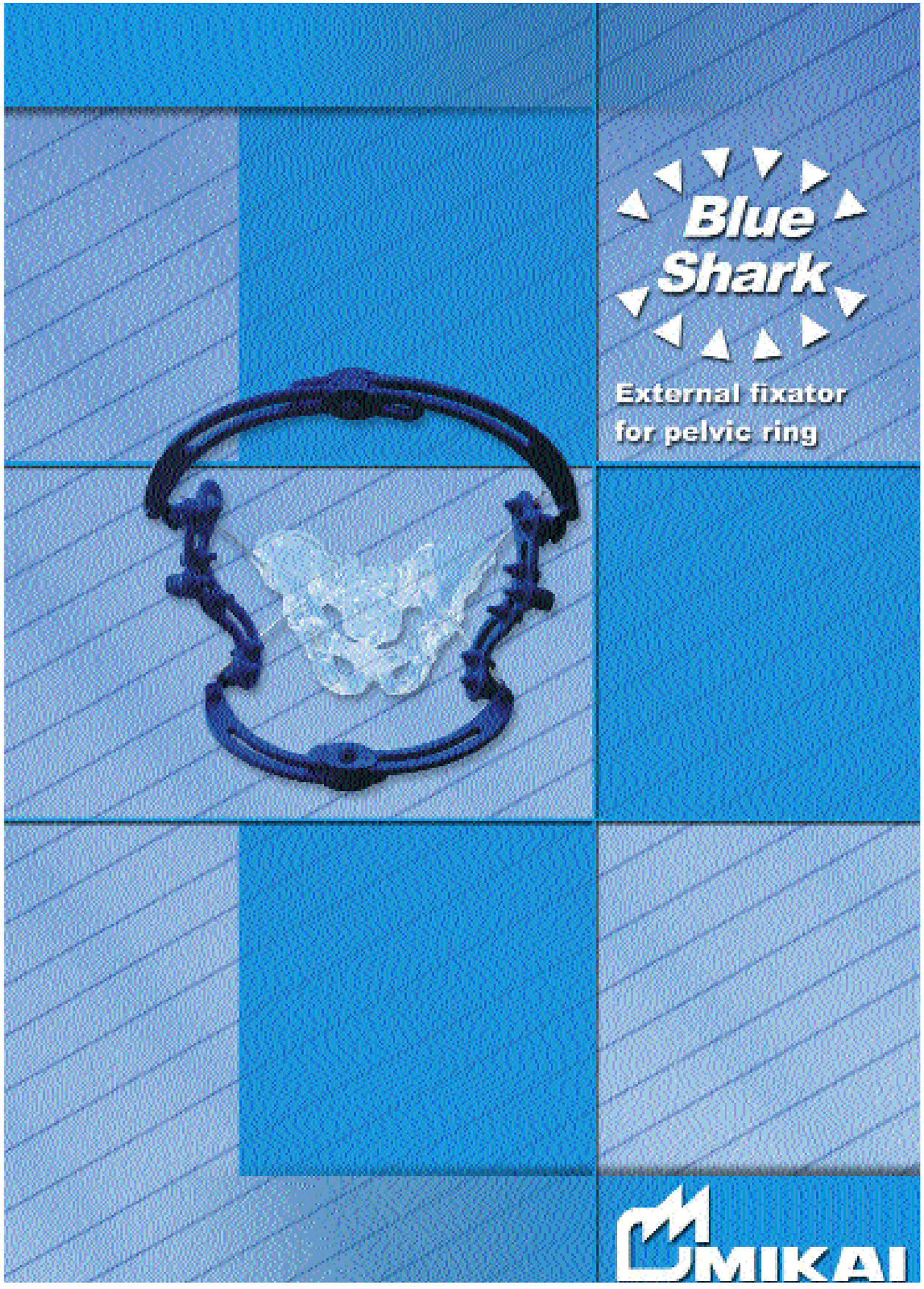


The **Blue Shark** radiolucent pelvic fixator for the pelvic ring was designed by the engineers at Mikai to mimic the anatomical structure of the pelvic girdle and developed using CAD/CAM software to project typical screw insertions.

The conditions we sought to achieve in the realization of this fixator were: quick implant, 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 in various hospital departments and with a varied level of expertise thanks to the ease of use and implantation of the fixator which allows for even one person alone to rapidly stabilize a pelvic ring fracture.

The radiolucent and magnet compatible qualities of the **Blue Shark** allow for thorough diagnosis of concurrent abdominal, cranial or medullary injuries as well as angiographic procedures or more complicated orthopedic procedures using radioscopic examination (ex. stabilization with percutaneous sacroiliac screws).

The configuration of the fixator can even be modified at a later time in order to obtain 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.

INDICATIONS FOR USE

Blue Shark is indicated for use in urgent situations for patients that require a rapid stabilization of complex fractures of the pelvic girdle 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 the AO classification (partially unstable fractures) and as a temporary remedy for type “C” fractures (generally unstable).

DESCRIPTION OF COMPONENTS

The fixator is composed of:

Two arced connectors. Each arc is made up of two semi-arcs in the form of a musical tuning fork joined by a ring that allows for a variation of the angle during the pelvic reduction. A third arc is an accessory to the kit which allows for further variations of the fixator configuration.

Two stirrups (right and left) mirror anatomical images that follow the physiological 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 arcs - these components are supplied pre-assembled on the stirrups.

Grasping components - 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 fix the screws to the clamps and clamp the connecting arcs in the desired position
- Disposable cannnula to protect the interface between the skin and the screw during implant
- Disposable smooth tipped trocar

CLINCAL CASE STUDIES

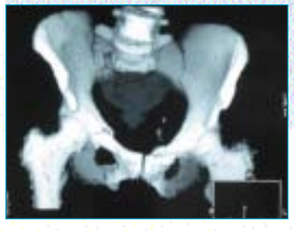
CASE PRESENTATION: 32 year old Male, motorcycle accident; type AO lesion B1.3

PREOP X-RAY

POSTOP X-RAY

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

PREOP CT SCAN



POSTOP X-RAY