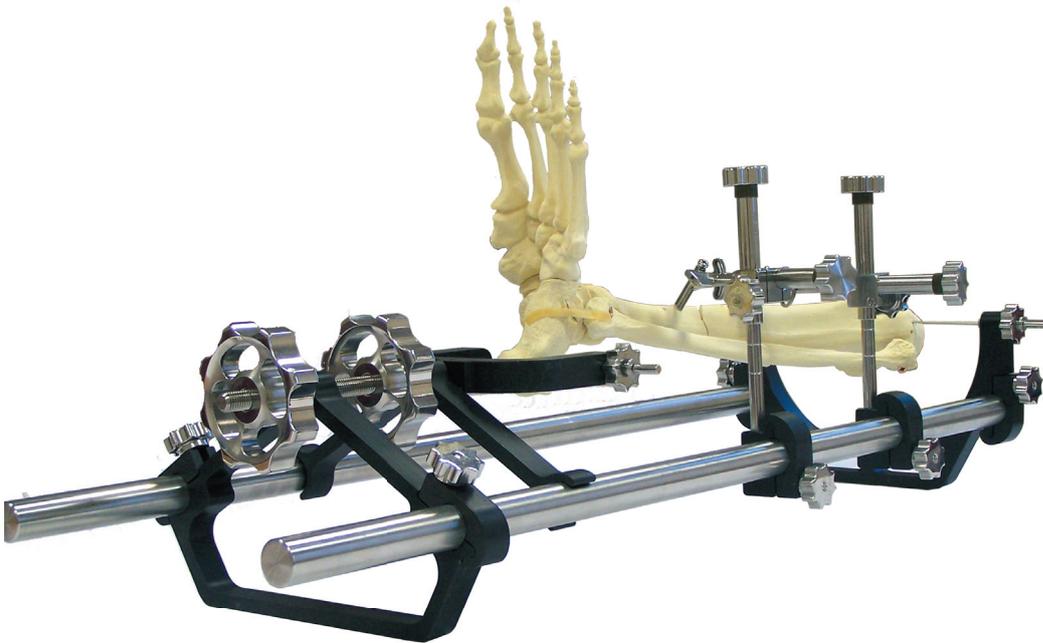


s · t · ϕ · r · m[®]

staffordshire orthopaedic reduction machine

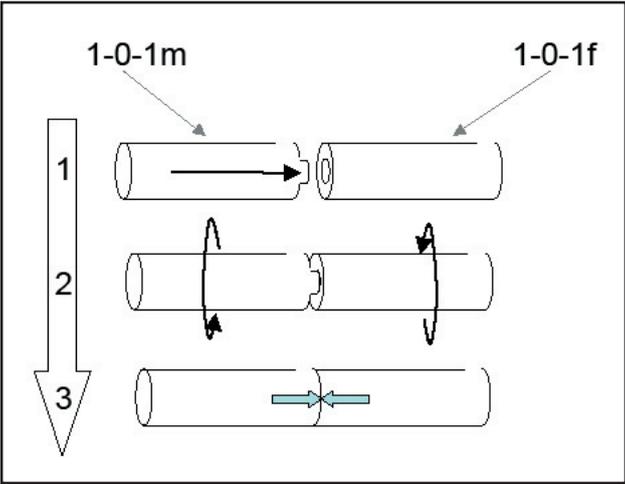


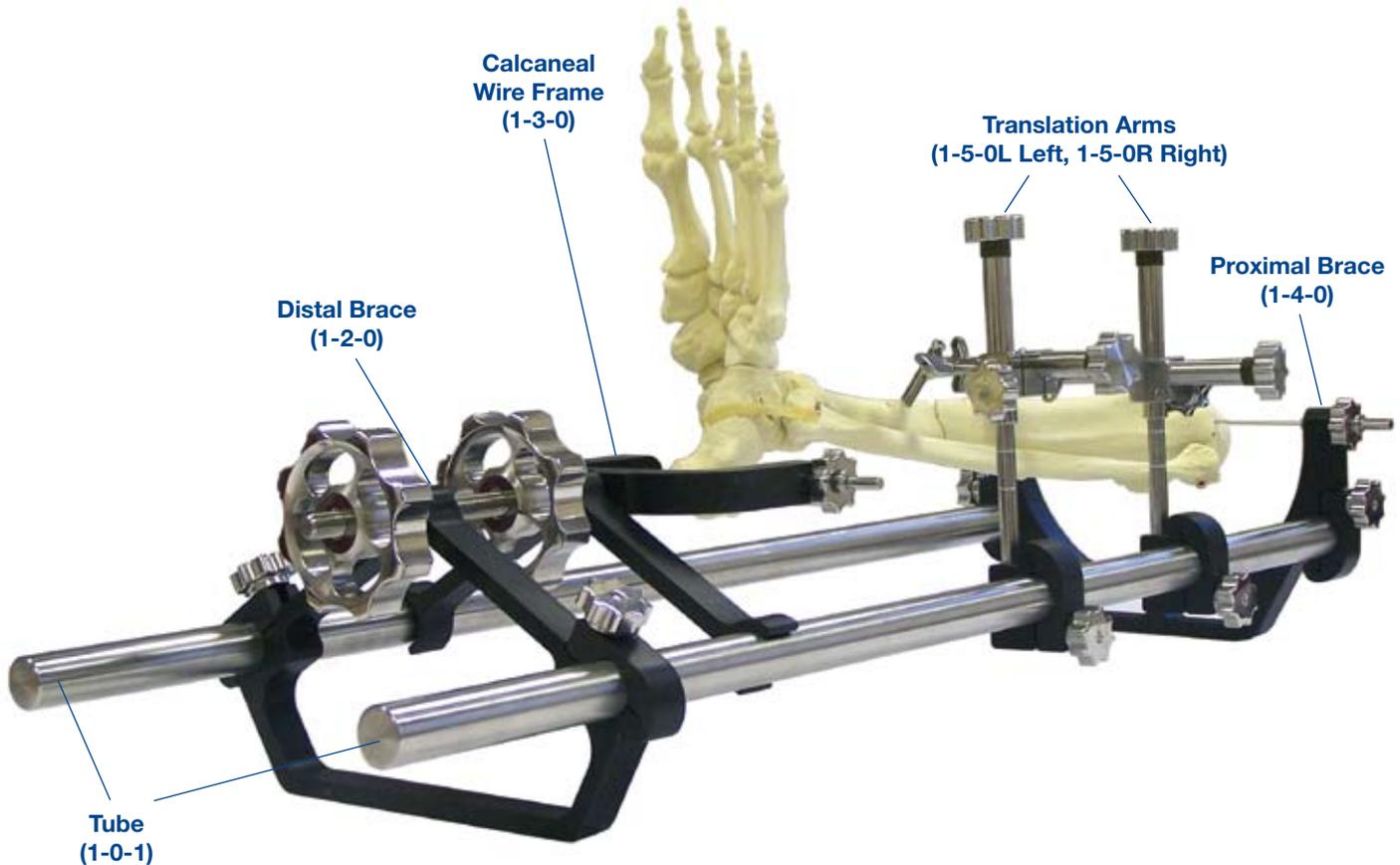
- **Assembly, Sterilisation and Cleaning Manual**
- **Servicing Programme**
- **Parts List**



intelligent orthopaedics

METAPHYSIS LLP





Assembly, Sterilisation and Cleaning Manual

Description

The Staffordshire Orthopaedic Reduction Machine, stφrm, is a class I re-usable device.

It has been designed to help the orthopaedic surgeon to reduce an unstable lower leg fracture prior to fixation. Used correctly it will help to achieve reliable reductions of high accuracy, shorter operating times, and more consistent operation durations. The device has four main sections as described below.

Proximal Brace Assembly

The proximal brace (1-4-0) is fixed to the ends of the two tubes (1-0-1), leaving about 10 mm extending, using the lateral and medial clamps (1-0-3). The tube (1-0-3) clamps are “biscuit jointed” components, this means that they fit together like a jigsaw piece; they are tightened using the clamp lock nuts (1-0-8). The stφrm kit contains a torque-grip (1-0-10) that fits all locking screws and nuts and can be used during the operation to achieve sufficient tightening torque.

The wire tensioners are pre-assembled as illustrated from the wire sleeve (1-0-4) and wire tension nut (1-0-6).

Distal Brace Assembly

The distal brace (1-0-2) is clamped to the tubes (1-0-1) in a similar manner to the proximal brace, however the clamp nuts (1-0-8) are only finger tightened before an operation starts, as this assembly slides to accommodate different limb lengths.

Calcaneal Wire Frame Assembly

To assemble, pass the threaded rod of the calcaneal wire frame (1-3-0) through the calcaneal brace (1-3-2) first, then screw on the traction nut (1-2-2), using the correct orientation described below.

NOTE: The two traction nuts (1-2-2) must be assembled in the correct orientation such that the bosses face proximally and these touch the bushes which face distally.

Next pass the rod through the distal brace (1-2-0) and screw on remaining traction nut (1-2-2); leave 10 mm of the rod protruding. During the operation traction can be applied with this nut. Looking from the distal end, turning the nut (1-2-2) clockwise applies traction, anti-clockwise releases.

In a similar way to the proximal brace the wire tensioner assembly (1-0-4 & 1-0-6) is always placed lateral, and the wire-clamp (1-0-5) is always medial. In all cases the calcaneal wire frame (1-0-3) starts horizontal. Unlocking the more proximal traction nut (1-2-2), adjusting and re-locking can alter the rotation of the calcaneal wire frame (1-3-0). Looking from the distal end, turning the proximal traction nut (1-2-2) clock-wise locks and anti-clockwise unlocks.

Translation Arm Assembly

For cleaning and sterilisation purposes the arms (1-5-0L and 1-5-0R) are fully disassembled. Prior to the operation the translation arms should be loosely assembled as illustrated, all screws and nuts should be finger tightened only. A separate laminate sheet provides detailed information on the assembly of the arms.

NOTE: The translation arms are only mounted on the frame mid-operation. It should be set central, two lines just showing (see last photo on page 4).

Sterilisation and storage case

The stōrm is supplied with a specific sterilisation tray, insert and lid (1-7-1, 1-7-2 and 1-7-3). Disassembly of the stōrm is simply a reverse of the process described above; a manifest is supplied. The storage case has been designed for use in standard cleaning and autoclave sterilisation units.

Cleaning and sterilisation

Intelligent Orthopaedics recommends that the cleaning and decontamination of instruments and devices following the guidelines set forth by MHRA, AORN/HIMA and AAMI.

A separate cleaning, decontamination and sterilisation guide is available as an Instruction for Use.

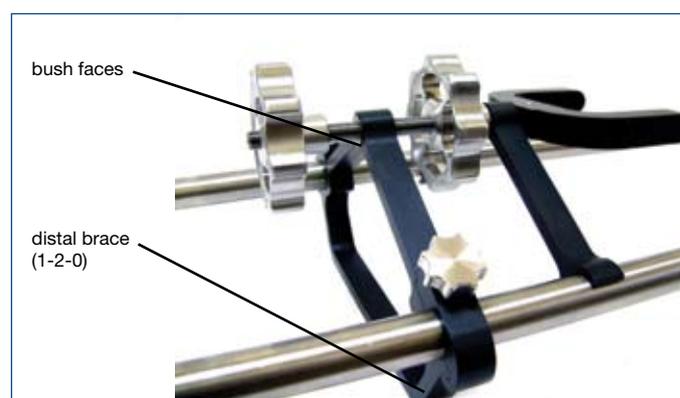
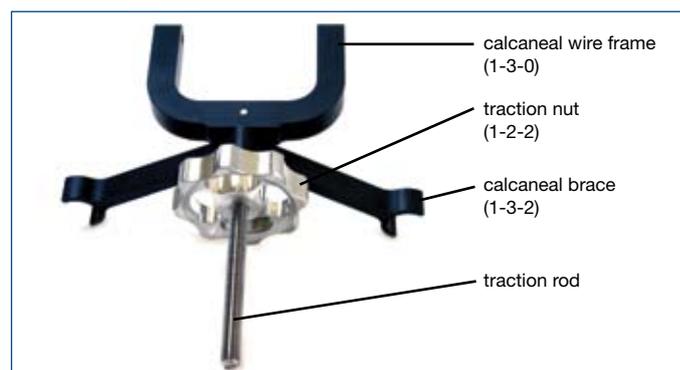
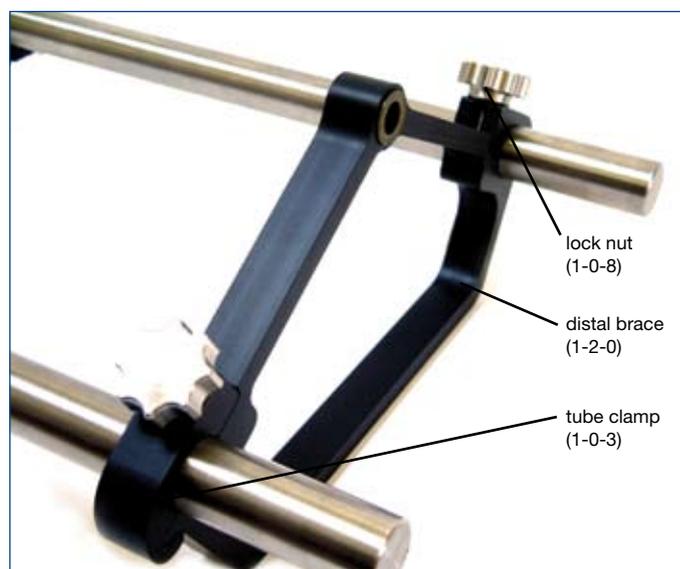
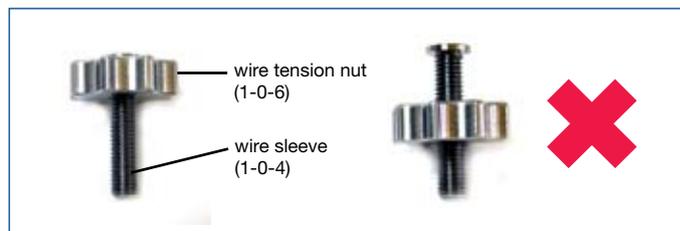
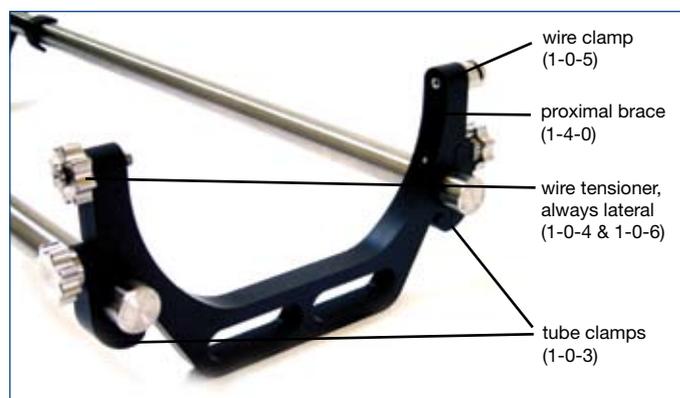
After sterilisation the device should be packaged, stored and transported in a manner that ensures sterility is maintained.

Do not use the instrument if it has not cooled sufficiently.

Do not re-use any of the consumable items, such as tension wires, uni-cortical screws, drill bits or bone screws.

Assembly prior to use

1. The device should be assembled in a sterile environment prior to use.
2. **Do not use** any items that appear to be damaged or whose sterility has been compromised.





Quick assembly instructions (translation arms)



1



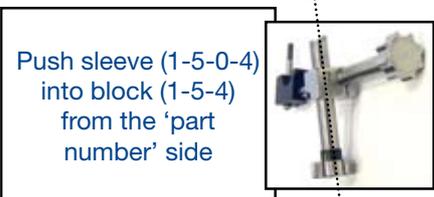
Hold block (1-5-4), with text facing upwards, insert sleeve (1-5-0-2) from the top

Screw column (1-5-0-1) into (1-5-0-2) up to middle line

Note: You will need to push 1-5-0-1 into 1-5-0-2 to engage

Note: You will need to push 1-5-0-3 into 1-5-0-4 to engage

2

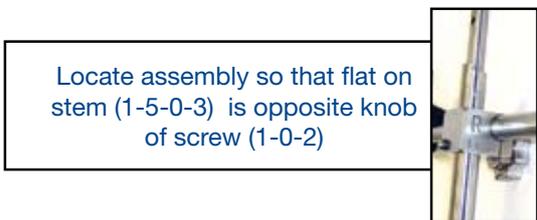


Push sleeve (1-5-0-4) into block (1-5-4) from the 'part number' side

Screw arm (1-5-0-3) into (1-5-0-4) up to middle line

Insert screw (1-0-2) from opposite side of text, do not tighten

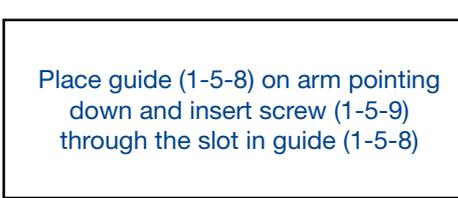
3



Locate assembly so that flat on stem (1-5-0-3) is opposite knob of screw (1-0-2)

Ensure that block (1-5-4) is central and tighten screw (1-0-2)

4



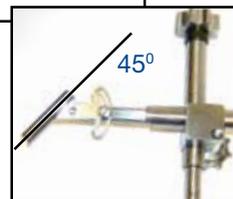
Place guide (1-5-8) on arm pointing down and insert screw (1-5-9) through the slot in guide (1-5-8)

Screw nut (1-5-10) onto screw (1-5-9), tighten lightly with guide at 45 degrees

5



Leave nut (1-0-8) and clamp (1-0-3) in tray



45°

Intelligent Orthopaedics, the IO logo and the s-t-φ-r-m logo are all trademarks of Intelligent Orthopaedics Ltd.

Distributed by

BSN medical Ltd.
Brierfield Mills, Brierfield, Nelson
Lancashire BB9 5NJ, UK
Tel. +44 1282 617744 www.bsnmedical.com
To order toll-free: BSN medical (+1) 800 552 1157



56290G RN

L-QUICKASSEMARM

Designed and manufactured by

Intelligent Orthopaedics Ltd.
Stoke on Trent, PO Box 2681
ST4 9BE, UK
Tel. +44 (0) 844 800 4405
www.intelligent-orthopaedics.co.uk



©2007 BSN medical, Inc.

REV 02/07

Servicing Programme

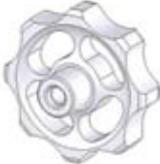
1. Servicing period every 25 sterilisations
2. Service recommendations
 - 2.1 A thorough manifest check should be conducted to ensure all parts are present and correct.
 - 2.2 Thorough de-scaling and cleaning of all threaded portions to remove cleaning and sterilisation residues.
 - 2.3 Thorough inspection of all bushes for signs of wear, damage or loosening. If any bush is damaged, loose or excessively worn then the bush / part should be replaced.
 - 2.4 Thorough inspection of all studs for signs of damage. If any stud is deemed bent or damaged then the corresponding part should be replaced.
 - 2.5 Thorough inspection of all main members for signs of damage, crack propagation, and excessive wear. If any sign is visible the part should be replaced.
 - 2.6 After servicing the stporm should be pre-assembled and all moving parts checked for free running. If any tightness is exhibited 2.2-2.5 should be repeated.



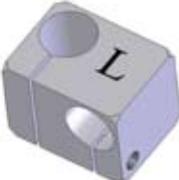
storm Parts List (1-0-0)

Part Number	NART Code	Description	Quantity Per storm	Image
1-0-1	73433-00000-01	Tube	2	
1-0-2	73433-00032-00	Translation Arm Lock Screw	2	
1-0-3	73433-00006-00	Tube Clamp	6 (4 in main assembly and 1 in each translation arm subassembly)	
1-0-4	73433-00009-00	Wire Sleeve	2	
1-0-5	73433-00010-00	Wire Clamp	2	
1-0-6	73433-00008-00	Wire Tension Nut	2	
1-0-8	73433-00007-00	Lock Nut	6 (4 in main assembly and 1 in each translation arm subassembly)	

storm Parts List (1-0-0)

Part Number	NART Code	Description	Quantity Per storm	Image
1-0-10	73433-00011-00	Torque Grip	1	
1-2-0	73433-00002-00	Distal Brace	1	
1-2-2	73433-00005-00	Traction Nut	2	
1-3-0	73433-00004-00	Calcaneal Wire Frame	1	
1-3-2	73433-00003-00	Calcaneal Brace	1	
1-4-0	73433-00001-00	Proximal Brace	1	
1-5-0-1	73433-00018-00	Translation Arm Column	2	

storm Parts List (1-0-0)

Part Number	NART Code	Description	Quantity Per storm	Image
1-5-0-2	73433-00018-00	Translation Arm Column Sleeve	2	
1-5-0-3	73433-00019-00	Translation Arm Beam	2	
1-5-0-4	73433-00019-00	Translation Arm Beam Sleeve	2	
1-5-4	73433-00024-00	Translation Arm Block - Left	1	
1-5-5	73433-00025-00	Translation Arm Block - Right	1	
1-5-8	73433-00020-00	Bone Screw Guide	2	
1-5-9	73433-00021-00	Guide Lock Screw	2	

storm Parts List (1-0-0)

Part Number	NART Code	Description	Quantity Per storm	Image
1-5-10	73433-00022-00	Guide Lock Nut	2	
1-6-1	73433-00016-00	3.2 mm Drill Guide	1	
1-6-3	73433-00014-00	Trocar	1	
1-7-1	73433-00017-01	Sterilisation Case Base	1	
1-7-2	73433-00017-01	Sterilisation Case Lid	1	
1-7-3	73433-00017-01	Sterilisation Case Tray	1	
1-5-0L	73433-00012-00	Translation Arm Left	1	
1-5-0R	73433-00013-00	Translation Arm Right	1	

Intelligent Orthopaedics, the IO logo and the storm logo are all trademarks of METAPHYSIS LLP



Distributed by

Designed and manufactured by

Metaphysis LLP
Keele
Staffordshire
UK ST5 5HH
www.io-uk.com
info@io-uk.com

